

# **EXHIBIT A**

BUTLER | SNOW

March 28, 2013

Via E-Mail [tcartmell@wagstffcartmell.com](mailto:tcartmell@wagstffcartmell.com)

Tom P. Cartmell, Esq.  
WAGSTAFF & CARTMELL, LLP  
4740 Grand Avenue, Suite 300  
Kansas City, MO 64112

Re: Pelvic Mesh

Dear Tom:

This letter follows our meet and confer on Friday, March 22, 2013, regarding the 30(b)(6) Design Notice which seeks testimony regarding the "Standard Operating Procedures (SOP) associated with design and development of the Devices" and seeks the production of several categories of documents related to Procedures (see 5(c), (d), (j), (k), (n), (o), (r), 6(a), (b), (c), (d)). This issue was also addressed in your letter dated March 19, 2013. We write to specifically address the production of Procedures. We will respond to the other items that were the subject of our call in a separate letter that will be sent shortly.

During our call, you requested that we produce an index of all Standard Operating Procedures for Ethicon. You suggested that you would review the index and then let us know which of the Procedures Plaintiffs want copies.

Enclosed is a partial list of Procedures from the following departments: Risk Management, Research and Development, Product Performance Evaluation, Regulatory, and Quality Assurance. As noted, this is a partial list of the Company's procedures; it will take a significant amount of time to confirm this is a complete list. As we have stated to you, the vast majority of these procedures have no relevance to Plaintiffs' claims. Accordingly, we ask that you review the enclosure and let us know which of these Procedures that Plaintiffs request and the order of priority as quickly as possible.

As you know, Dan Lamont's deposition is set for April 3 and 4, 2013. At this time, we intend to produce to you in advance of the deposition the current version and the revision histories of the four procedures that Mr. Lamont uses most frequently, which are:

- PR0000118 Franchise Procedure for Product Complaint Management;
- PR 551-005 Company Procedure for Customer Complaint Management;
- PR 551-006 Work Instructions for Summary and Individual MDR Reporting; and
- PR0000385 Franchise Procedure for Post-Market Surveillance.

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Tom P. Cartmell, Esq.  
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We look forward to hearing from you soon and, as stated, are sending you a separate letter to address the other topics we discussed.

Sincerely,

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC



Chad R. Hutchinson

CRH:ljg

Enclosures

cc: Bryan Aylstock, Esq. (w/enc. via email @ baylstock@awkolaw.com)  
ButlerSnow 15880537v1

## Pelvic Mesh Adaptiv Export

Number	Business Unit	Title	Type	Class	Sub Class	Rev	Description	State
100074037	Ethicon Products, ,	Operating Procedure for Visual Inspection (Product Appearance) Using a Microscope, an Eyeloop, or the Naked Eye.	Work Instruction (Non-PPE)	Quality System	Inspection and Testing	7	Operating Procedure for Visual Inspection (Product Appearance) Using a Microscope, an Eyeloop, or the Naked Eye.	Released
100081457	Ethicon Products, ,	Operating Procedure for Inspection and Disposition of Materials at a Supplier Facility or by Pre-Shipment Samples	Work Instruction (Non-PPE)	Quality System	Inspection and Testing	20	Operating Procedure for Inspection and Disposition of Materials at a Supplier Facility or by Pre-Shipment Samples	Released
100083526	Ethicon Products, ,	Operating Procedure For Documenting The Investigation Of Out Of Specification Test Results	Work Instruction (Non-PPE)	Quality System	Inspection and Testing	8	Operating Procedure For Documenting The Investigation Of Out Of Specification Test Results	Released
100083540	Ethicon Products, ,	PHOTOGRAPHIC STANDARDS OPERATING PROCEDURE	Work Instruction (Non-PPE)	Quality System	Inspection and Testing	10	PHOTOGRAPHIC STANDARDS OPERATING PROCEDURE	Released
NTB-070	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Procedure for Preparation, Approval, Maintenance, and Control of Procedures for Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	4	Procedure for Preparation, Approval, Maintenance, and Control of Procedures for Clinical Trials	Released
OP600-020	Ethicon Products, ,	Procedure for Maintaining a Trial Master File for Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	6 (7)	Procedure for Maintaining a Trial Master File for Clinical Trials	Released
OP600-020	Ethicon Products, J&J Wound Management, ,	Procedure for Maintaining an Investigator Trial File for Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	2 (3)	Procedure for Maintaining an Investigator Trial File for Clinical Trials	Released
OP600-039	Ethicon Products, J&J Wound Management, ,	Procedure for the Use of a Contract Research Organization for Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	3	Procedure for the Use of a Contract Research Organization for Clinical Trials	Released
OP600-040	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS PROCEDURE FOR SUPPLY AND ACCOUNTABILITY OF STUDY ARTICLES FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	Design and Development	2	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS PROCEDURE FOR SUPPLY AND ACCOUNTABILITY OF STUDY ARTICLES FOR CLINICAL TRIALS	Released
OP600-065	Ethicon Products, J&J Wound Management, ,	Procedure for Adverse Event Collection and Reporting for a Pharmaceutical Clinical Trial	Procedure (Non-PPE)	Quality System	Design and Development	2	Procedure for Adverse Event Collection and Reporting for a Pharmaceutical Clinical Trial	Released
OP600-072	Ethicon Products, J&J Wound Management, ,	Procedure for Adverse Event Collection and Reporting for U.S. Medical Device Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	2	Procedure for Adverse Event Collection and Reporting for U.S. Medical Device Clinical Trials	Released
OP607-182	Ethicon Products,	Ethicon Procedure for Developing a Project Specific Audit Plan (PSAP) for Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	2	Ethicon Procedure for Developing a Project Specific Audit Plan (PSAP) for Clinical Trials	Released
OP608-007	Ethicon Products, ,	Ethicon Procedure for Clinical Quality Assurance Reviews of Clinical Trial Protocols	Procedure (Non-PPE)	Quality System	Design and Development	2	Ethicon Procedure for Clinical Quality Assurance Reviews of Clinical Trial Protocols	Released
OP608-008	Ethicon Products, ,	Ethicon Procedure for Clinical Quality Assurance Audits of Clinical Trial Investigator Sites	Procedure (Non-PPE)	Quality System	Design and Development	3	Ethicon Procedure for Clinical Quality Assurance Audits of Clinical Trial Investigator Sites	Released
OP608-009	Ethicon Products, ,	Ethicon Procedure for Clinical Quality Assurance System Audits	Procedure (Non-PPE)	Quality System	Design and Development	3	Ethicon Procedure for Clinical Quality Assurance System Audits	Released
OP608-011	Ethicon Products, ,	Ethicon Procedure for Clinical Quality Assurance Audits of Clinical Study Reports	Procedure (Non-PPE)	Quality System	Design and Development	4	Ethicon Procedure for Clinical Quality Assurance Audits of Clinical Study Reports	Released
OP608-012	Ethicon Products, ,	Ethicon Procedure for Clinical Quality Assurance For-Cause Audits	Procedure (Non-PPE)	Quality System	Design and Development	3	Ethicon Procedure for Clinical Quality Assurance For-Cause Audits	Released
OP609-028	Ethicon Products, ,	Ethicon Procedure for Clinical Quality Assurance Audits of Clinical Trial Vendors	Procedure (Non-PPE)	Quality System	Design and Development	4	Ethicon Procedure for Clinical Quality Assurance Audits of Clinical Trial Vendors	Released
OP612-011	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Procedure for Registration, Assessment and Disclosure of Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	2	Procedure for Registration, Assessment and Disclosure of Clinical Trials	Released
PR-0000009	Women's Health and Urology, ,	Company Procedure for Product End of Life Management	Procedure (Non-PPE)	Quality System	Design and Development	1	Company Procedure for Product End of Life Management	Released
PR-0000012	Women's Health and Urology, ,	PROCEDURE FOR PROCESS DEVELOPMENT OF ELECTROMECHANICAL DEVICES also training Powerpoint presentation.	Procedure (Non-PPE)	Quality System	Design and Development	1 (2)	PROCEDURE FOR PROCESS DEVELOPMENT OF ELECTROMECHANICAL DEVICES also training Powerpoint presentation.	Released
PR-0000020	Women's Health and Urology,	PROCEDURE FOR PROCESS VALIDATION OF ELECTROMECHANICAL PRODUCTS	Procedure (Non-PPE)	Quality System	Design and Development	2	PROCEDURE FOR PROCESS VALIDATION OF ELECTROMECHANICAL PRODUCTS	Released
PR-0000110	Women's Health and Urology,	PROCEDURE FOR MANUFACTURING TEST & INSPECTION OF ELECTROMECHANICAL DEVICES	Procedure (Non-PPE)	Quality System	Design and Development	2	PROCEDURE FOR MANUFACTURING TEST & INSPECTION OF ELECTROMECHANICAL DEVICES	Released
PR-0000172	Ethicon Products, J&J Wound Management, Women's Health and Urology,	ETHICON COMPANY PROCEDURE FOR INTERPRETATION OF NEW PRODUCT DEVELOPMENT DRAWINGS	Procedure (Non-PPE)	Quality System	Design and Development	1	ETHICON COMPANY PROCEDURE FOR INTERPRETATION OF NEW PRODUCT DEVELOPMENT DRAWINGS	Released
PR-0000175	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Managing Validation Documentation in the ADAPTIV System	Work Instruction (Non-PPE)	Quality System	Validation	2	na	Released
PR-0000191	Ethicon Products, ,	Assembly sheet procedure for D-Special products	Work Instruction (Non-PPE)	Quality System	Inspection and Testing	25	Assembly sheet procedure for D-Special products	Released
PR-0000200	Ethicon Products, ,	DESCRIPTIVE STATISTICS FOR ATTRIBUTE SAMPLING PLANS	Procedure (Non-PPE)	Quality System	Inspection and Testing	9	DESCRIPTIVE STATISTICS FOR ATTRIBUTE SAMPLING PLANS	Released
PR-0000216	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Company Procedure for Test Method Validation	Procedure (Non-PPE)	Quality System	Validation	12	Company Procedure for Test Method Validation	Released

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PR-0000639	Ethicon-Somerville-Product Performance Evaluation	Administration of Test Method Documents Controlled within the Somerville New Jersey Performance Evaluation Group	Procedure			1		
PR562-001	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Clinical Development and Medical Affairs Product Complaint and Adverse Event (AE) Reporting Process for Post-Approval Medical Device Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	4	Clinical Development and Medical Affairs Product Complaint and Adverse Event (AE) Reporting Process for Post-Approval Medical Device Clinical Trials	Released
PR572-001	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS WORK INSTRUCTIONS FOR SAS PROGRAM TESTING	Work Instruction (Non-PPE)	Quality System	Validation	3	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS WORK INSTRUCTIONS FOR SAS PROGRAM TESTING	Released
PR600-008	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Process Specification for Clinical Development Employee Training Records - Kirkton Campus	Work Instruction (Non-PPE)	Quality System	Design and Development	2	Process Specification for Clinical Development Employee Training Records - Kirkton Campus	Released
PR600-010	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCESS SPECIFICATION FOR REVIEW OF DISCLOSABLE FINANCIAL INTERESTS OF INVESTIGATORS IN US CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	Design and Development	1	PROCESS SPECIFICATION FOR REVIEW OF DISCLOSABLE FINANCIAL INTERESTS OF INVESTIGATORS IN US CLINICAL TRIALS	Released
PR800-002	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCESS SPECIFICATION FOR MAINTAINING A TRIAL MASTER FILE FOR CLINICAL TRIALS IN EU	Procedure (Non-PPE)	Quality System	Design and Development	1 (2)	PROCESS SPECIFICATION FOR MAINTAINING A TRIAL MASTER FILE FOR CLINICAL TRIALS IN EU	Released
PR800-013	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCESS SPECIFICATION FOR MAINTAINING A TRIAL MASTER FILE FOR CLINICAL TRIALS In US	Procedure (Non-PPE)	Quality System	Design and Development	2 (3)	PROCESS SPECIFICATION FOR MAINTAINING A TRIAL MASTER FILE FOR CLINICAL TRIALS In US	Released
PR800-014	Ethicon Products,	Process Specification for Review of Micro-Needle Quality Data	Procedure (Non-PPE)	Quality System	Inspection and Testing	2	Process Specification for Review of Micro-Needle Quality Data	Released
PR800-027	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Process Specification For The Translation Of Clinical Study Documentation	Procedure (Non-PPE)	Quality System	Design and Development	1	Process Specification For The Translation Of Clinical Study Documentation	Released
PR850-006	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Independent Ethics Committee / Institutional Review Board Selection and Review for Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	1	Independent Ethics Committee / Institutional Review Board Selection and Review for Clinical Trials	Released
WI-0013213	Ethicon-Somerville-Product Performance Evaluation	Company Procedure for Reporting Test Results for Fibrin Pad	Procedure (Non-PPE)	Quality System	Design and Development Document Mgmt and Data Control Inspection and Testing	1	New Company Procedure for Reporting of Test Results, to Omrix Biopharmaceuticals, for Omrix Fibrin Pad Samples	Released
WI-0013214	Ethicon-Somerville-Product Performance Evaluation	Procedure for Sample managment of Fibrin Pad samples from Omrix	Procedure (Non-PPE)	Quality System	Design and Development Document Mgmt and Data Control Identification and Traceability	1	New Company Procedure for the sample management and traceability of Omrix Fibrin Pad non-stability samples submitted to Ethicon R & D Somerville	Released
100020238	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Action Task Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	5	na	Released
100020239	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Approval Matrix Work Instruction	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	3	na	Released
100020240	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Change Analyst Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Compliance Document Mgmt and Data Control	2	na	Released
100021301	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Change Control Objects Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	5	na	Released
100021311	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Equipment, Tooling and Gauges Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
100021313	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Values for Global Document Hierarchy Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	4	na	Released
100021316	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Main Part Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	4	na	Released
100021319	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Part Routings Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	5	na	Released
100021322	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for PC Part Master-Part Plants NA Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	10 (11)	na	Released
100021325	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for PC Relationships Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	4	na	Released
100021333	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Plant Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
100021601	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Approval Groups Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	7	na	Released

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100021602	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Impact Assessments Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
100021603	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Periodic Review Record Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
100021620	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Person Template Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
100021628	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Master Validation Index Change ProjectTemplate Config. Work Inst.	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control Validation	1	na	Released
100021630	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for PC Part Master-Part Plant EMS UDC Config. Work Instructions	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
100021635	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Validation Document Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control Validation	2 (3)	na	Released
100021646	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Product Design Change Project Template Configuration Work Instr	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control Validation	1	na	Released
100024690	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Non Product Process or Equipment Change Project Template Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control Validation	1	Ethicon Non Product Process or Equipment Change Project Template Configuration Work Instruction	Released
100024702	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Process or Equipment Change Project Template Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control Validation	1	Ethicon Process or Equipment Change Project Template Configuration Work Instruction	Released
100028505	Ethicon Products,	ADAPTIV Change Management Approval Business Rules and Matrices	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	2	na	Released
100028622	Ethicon Products,	ADAPTIV Paper-Based Change Management Process	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
100032163	Ethicon Products,	Test Document for Release 1.2.4 (CW Schedule Release Date)	Policy	Quality System	Document Mgmt and Data Control	1	na	Released
100033039	Ethicon Products, J&J Wound Management, Women's Health and Urology,	North America Validation Approval Matrix	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	3	na	Released
100033141	Ethicon Products, J&J Wound Management, Women's Health and Urology,	North America Approval Matrix	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	4 (5)	na	Released
100033693	Ethicon Products,	North America Part and BOM/DMR Change Instructions and Approval Matrix for ADAPTIV	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
100034326	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon NPD Project Template Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control Validation	1	na	Released
100034961	Ethicon-Somerville-WW Quality System	ADAPTIV PLM Installation Qualification for D3 Configuration and User Load	Protocol			1		
100034961	Ethicon-Somerville-WW Quality-Post Market Surveillance	ADAPTIV PLM Installation Qualification for D3 Configuration and User Load	Protocol			1		
100035998	Ethicon Products, J&J Wound Management, Women's Health and Urology,	ERP Transactions and Flat Files Work Instruction for JD Edwards North America	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
100036348	Ethicon Products, J&J Wound Management, Women's Health and Urology,	New Product Development Process in the ADAPTIV System	Procedure (Non-PPE)	Quality System	Design and Development	1 (2)	na	Released
100038279	Ethicon-Somerville-Quality Systems and Compliance	Increase of ECNT Sample Size for 28-mil PS-1 Needles	Protocol			1		
100040270	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CLINICAL DEVELOPMENT SITE BUDGETS AND CONTRACTS	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
100040270	Women's Health and Urology,	Service Bulletin for Duplicate Serial Numbers	Work Instruction (Non-PPE)	Quality System	Servicing	1	na	Released
100041959	Women's Health and Urology,	Quality Agreement between Ethicon and JnJ Medical, Shanghai Inc. for Service and Repair	Procedure (Non-PPE)	Quality System	Compliance	1	Original Quality Agreement.	Released
100043281	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Range Value Holders for Stagegate Objects Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control Validation	3 (4)	na	Released
100043767	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Anatomy, Physiology and Disease State Educational Materials	Procedure (Non-PPE)	Quality System	Communication	1	na	Released

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100045183	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Approval of Advertising and Promotional Claims for Medical Devices and Combination Products	Procedure (Non-PPE)	Quality System	Communication	1	na	Released
100045197	Ethicon Products, J&J Wound Management, Mentor, Women's Health and Urology,	Company Procedure for the Management and Traceability of Stability Samples	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	Company Procedure for the Management and Traceability of Stability Samples	Released
100048257	Women's Health and Urology,	Ethicon/Ethicon Endo Surgery LLC Quality Agreement	Work Instruction (Non-PPE)	Quality System	Servicing	1	Initial Quality Agreement between Ethicon Inc. and Ethicon Endo Surgery LLC	Released
100048899	Women's Health and Urology,	Service Bulletin to Release Initial Thermachoice Documentation to EES Service Center	Work Instruction (Non-PPE)	Quality System	Servicing	1	Provide EES Service Center with Service Manual, Service Procedures, Service Bulletins for Thermachoice.	Released
100048912	Ethicon-Somerville-WW Quality System	JDE NA Part Plant Release Levels	Protocol			1		
100048912	Ethicon-Somerville-WW Quality-NPI/LCM	JDE NA Part Plant Release Levels	Protocol			1		
100049547	Ethicon-Somerville-Quality Systems and Compliance	Addition of sites to the ADAPTIV User Profile Site Locations	Protocol			1		
100049547	Ethicon-Somerville-WW Quality-NPI/LCM	Addition of sites to the ADAPTIV User Profile Site Locations	Protocol			1		
100049548	Women's Health and Urology,	Service Bulletin to Release Initial Motor Drive Unit Documentation to EES Service Center	Work Instruction (Non-PPE)	Quality System	Servicing	1	Release service manual, procedures and service bulletins to EES.	Released
100049549	Women's Health and Urology,	Service Bulletin to Update Thermachoice Service Manual Part Numbers	Work Instruction (Non-PPE)	Quality System	Servicing	1	Update service manual to reflect correct service part numbers.	Released
100050148	Ethicon-Somerville-Quality Systems and Compliance	Production Protocol to Run the Current Die Set-Ups for Five Wire Types	Protocol			1		
100050280	Ethicon-Somerville-WW Quality System	Corrupt Lab Document LAB-0011029	Protocol			1		
100050280	Ethicon-Somerville-WW Quality-NPI/LCM	Corrupt Lab Document LAB-0011029	Protocol			1		
100050287	Ethicon-Somerville-WW Quality System	Revise Release Date for Brazil 60 Migrated Documents	Protocol			1		
100050287	Ethicon-Somerville-WW Quality-NPI/LCM	Revise Release Date for Brazil 60 Migrated Documents	Protocol			1		
100050293	Ethicon-Somerville-Quality Systems and Compliance	ACMS Migrated Documents - Change Validation Documents to Non-PPE Work Instructions	Protocol			1		
100050293	Ethicon-Somerville-WW Quality-NPI/LCM	ACMS Migrated Documents - Change Validation Documents to Non-PPE Work Instructions	Protocol			1		
100050312	Ethicon-Somerville-WW Quality Compliance	ACMS Objects linked to Cancelled CO's	Protocol			1		
100050312	Ethicon-Somerville-WW Quality-NPI/LCM	ACMS Objects linked to Cancelled CO's	Protocol			1		
100050846	Ethicon Products,	Ethicon D Special Change Project Template Configuration Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control/Validation	1	Ethicon D Special Change Project Template Configuration Work Instruction	Released
100050851	Ethicon Products,	Quality Agreement for Ethicon and Medical Device & Diagnostic (MD&D) ASEAN	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	1	Quality Agreement for Ethicon and Medical Device & Diagnostic (MD&D) ASEAN consisting of the Marketing companies in Malaysia, Thailand, Indonesia, Singapore, Vietnam & Philippines	Released
100051801	Women's Health and Urology,	Service Bulletin for Versapoint CPU Board Change	Work Instruction (Non-PPE)	Quality System	Servicing	1	This Service Bulletin provides instructions for the Versapoint CPU Board.	Released
100053051	Ethicon-Somerville-Quality Systems and Compliance	Process Verification Protocol for 5H and 8H Die Line Ups	Protocol			1		
100053669	Women's Health and Urology,	Service Bulletin for Versapoint Non-GTS Burn-In Fixture	Work Instruction (Non-PPE)	Quality System	Servicing	1	Service Bulletin to modify Versapoint Non-GTS Burn-In Fixture, Part number: GML3744, to increase the load resistance. This change is documented in Gyrus Field/Service Center Bulletin number 806000 - Serial 016	Released
100055291	Ethicon Products, J&J Wound Management, Women's Health and Urology,	VALIDATING EDIT CHECKS USING ELECTRONIC DATA CAPTURE	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
100055293	Ethicon Products, J&J Wound Management, Women's Health and Urology,	USER ACCEPTANCE TESTING (UAT) USING ELECTRONIC DATA CAPTURE (EDC)	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
100055630	Ethicon Products, J&J Wound Management, Women's Health and Urology,	STUDY HOLD, INTERIM ANALYSIS AND STUDY CLOSURE USING ELECTRONIC DATA CAPTURE (EDC)	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
100056398	Ethicon Products, J&J Wound Management, Women's Health and Urology,	SITE READINESS WHEN USING ELECTRONIC DATA CAPTURE (EDC)	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
100056672	Ethicon-Somerville-Quality Systems and Compliance	JDE NA Part Plant Release Levels	Protocol			1		
100056672	Ethicon-Somerville-WW Quality-NPI/LCM	JDE NA Part Plant Release Levels	Protocol			1		
100056677	Ethicon-Somerville-Quality Systems and Compliance	Morcellex Drawing Revision Letters	Protocol			1		
100056677	Ethicon-Somerville-WW Quality-NPI/LCM	Morcellex Drawing Revision Letters	Protocol			1		
100056934	Ethicon-Somerville-Quality Systems and Compliance	ADAPTIV WI Number Change to EBOM Number	Protocol			1		

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100056934	Ethicon-Somerville-WW Quality-NPI/LCM	ADAPTIV WI Number Change to EBOM Number	Protocol			1			
100056993	Ethicon Products, J&J Wound Management, Women's Health and Urology,	REPORTING WITHIN ELECTRONIC DATA CAPTURE (EDC) STUDIES	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na		Released
100057141	Ethicon Products, J&J Wound Management, Women's Health and Urology,	GUIDELINE FOR UTILIZING THE LAB ADMINISTRATION MODULE IN MEDIDATA RAVE	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na		Released
100057221	Ethicon-Somerville-Quality Systems and Compliance	Unable to Open MS-000309 V2	Protocol			1			
100057221	Ethicon-Somerville-WW Quality-NPI/LCM	Unable to Open MS-000309 V2	Protocol			1			
100057226	Ethicon-Somerville-Quality Systems and Compliance	Franchise Procedure Revision Number Correction	Protocol			1			
100057226	Ethicon-Somerville-WW Quality-NPI/LCM	Franchise Procedure Revision Number Correction	Protocol			1			
100057648	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CHANGE CONTROL PROCESSES FOR ELECTRONIC DATA CAPTURE (EDC)	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na		Released
100057658	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CREATION AND APPROVAL OF AN ELECTRONIC CRF FOR USE IN ELECTRONIC DATA CAPTURE	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na		Released
100057729	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR MEDIDATA RAVE SYSTEM SECURITY AND DISASTER RECOVERY	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na		Released
100058365	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Mass BOM/DMR Extract, Create and Edit Tool	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na		Released
100058839	Ethicon-Somerville-WW Quality System	ADAPTIV PLM System Test Protocol Release 1.2.6	Protocol			1			
100058839	Ethicon-Somerville-WW Quality-NPI/LCM	ADAPTIV PLM System Test Protocol Release 1.2.6	Protocol			1			
100059024	Ethicon Products, J&J Wound Management, Women's Health and Urology,	ESTABLISHMENT AND OPERATION OF DATA MONITORING COMMITTEES OR DATA SAFETY MONITORING BOARD	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na		Released
100060373	Ethicon-Somerville-Quality Systems and Compliance	Revise the Number and Legacy Revision of Drawing	Protocol			1			
100060373	Ethicon-Somerville-WW Quality-NPI/LCM	Revise the Number and Legacy Revision of Drawing	Protocol			1			
100060417	Ethicon-Somerville-WW Quality System	Adaptive Installation Qualification for Release 1.2.6	Protocol			1			
100060417	Ethicon-Somerville-WW Quality-NPI/LCM	Adaptive Installation Qualification for Release 1.2.6	Protocol			1			
100060490	Ethicon-Somerville-WW Quality System	PC Range Values with Extra Spaces	Protocol			1			
100060490	Ethicon-Somerville-WW Quality-NPI/LCM	PC Range Values with Extra Spaces	Protocol			1			
100060520	Ethicon-Somerville-Quality Systems and Compliance	Protocol for product dose mapping of Surgiflo Endoscopic Applicators at Steris Whippany, NJ	Protocol			1			
100060533	Ethicon-Somerville-Quality Systems and Compliance	Protocol for product dose mapping of X-Tract Laparoscopic Tissue Morcellator at Steris Whippany, NJ	Protocol			1			
100060539	Ethicon-Somerville-Quality Systems and Compliance	Protocol for product dose mapping of Morcellex Laparoscopic Tissue Morcellator at Steris Whippany NJ	Protocol			1			
100060542	Ethicon-Somerville-Quality Systems and Compliance	Protocol for product dose mapping of Stainless Steel Suture at Steris Whippany, NJ	Protocol			1			
100060548	Ethicon-Somerville-Quality Systems and Compliance	Protocol for isodose profile of homogeneous absorbers at Steris Whippany Ni	Protocol			1			
100060562	Ethicon-Somerville-Quality Systems and Compliance	Protocol for product dose mapping of Hemo family product at Steris Whippany, NJ	Protocol			1			
100060563	Ethicon-Somerville-Quality Systems and Compliance	Protocol for product dose mapping of Interceed family at Steris Whippany, NJ	Protocol			1			
100061954	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Procedure for Establishment Registration and Medical Device Listing	Procedure (Non-PPE)	Quality System	Compliance Record Management	1	na		Released
100063307	Ethicon-Somerville Plant-Quality Engineering	Sentinel Pre-Clinical Build Protocol	Protocol			2			
100063307	Ethicon-Somerville Plant-Quality Engineering	Sentinel Pre-Clinical Build Protocol	Protocol			1			
100065070	Ethicon Products, J&J Wound Management, Women's Health and Urology,	ROUTINE ADVERSE EVENT REVIEW FOR POTENTIAL SAFETY SIGNALS/TRENDS ON INVESTIGATIONAL CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na		Released
100065085	Ethicon Products,	Quality Agreement for Ethicon and Johnson & Johnson Medical (Suzhou) Ltd.	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	1	Quality Agreement for Ethicon and Johnson & Johnson Medical (Suzhou) Ltd. Asia Pacific Regional Design Centre, Suzhou (JJMSZ R&D Quality Agreement Rev. A)	Released	
100065418	Ethicon-Somerville-Quality Systems and Compliance	Brazil MVI's Change from Retired to Exist	Protocol			1			
100065418	Ethicon-Somerville-WW Quality-NPI/LCM	Brazil MVI's Change from Retired to Exist	Protocol			1			
100067515	Ethicon Products, J&J Wound Management,	JDE OneWorld Manually Enter/Revise/Process Purchase Orders	Work Instruction (Non-PPE)	Quality System	Planning	3	JDE OneWorld Manually Enter/Revise/Process Purchase Orders	Released	

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100068548	Ethicon Products, J&J Wound Management, ,	JDE OneWorld Manually Process Debit PO's	Work Instruction (Non-PPE)	Quality System	Planning	1	JDE OneWorld Manually Process Debit PO's	Released
100069537	Ethicon Products, J&J Wound Management, ,	JDE OneWorld Enter/Revise/Process Adjustmeent Purchase Orders	Work Instruction (Non-PPE)	Quality System	Planning	2	JDE OneWorld Enter/Revise/Process Adjustmeent Purchase Orders	Released
100071041	Ethicon-Somerville-Quality Systems and Compliance	PQ protocol for Dry Heat Batch Oven	Protocol			1		
100071170	Ethicon-Somerville-Quality Systems and Compliance	Dose Distribution Study for PROCEED Processed at STERIS Spartanburg, SC	Protocol			1		
100074037	Ethicon Products, ,	Operating Procedure for Autoclave.	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	5	Operating Procedure for Autoclave.	Released
100074068	Ethicon Products, J&J Wound Management, Women's Health and Urology,	OPERATING PROCEDURE FOR QUARTERLY ETHYLENE OXIDE BIOBURDEN AUDIT PROGRAM	Procedure (Non-PPE)	Quality System	Sterilization and Microbiology	68 (69)	OPERATING PROCEDURE FOR QUARTERLY ETHYLENE OXIDE BIOBURDEN AUDIT PROGRAM	Released
100074068	Ethicon Products, ,	OPERATING PROCEDURE FOR QUARTERLY PARTICULATE COUNT AUDIT IN CONTROLLED MANUFACTURING AREA & MICRO	Procedure (Non-PPE)	Quality System	Sterilization and Microbiology	46 (47)	OPERATING PROCEDURE FOR THE QUARTERLY PARTICULATE COUNT AUDIT CONDUCTED INSIDE THE CONTROLLED MANUFACTURING ENVIRONMENT (ENVIRONMENT CONTROL LEVEL #2) AND MICROBIOLOGY DEPARTMENT	Released
100074074	Ethicon Products, ,	OPERATING PROCEDURE FOR THE DISINFECTION OF MICROBIOLOGY INCUBATORS, MEDIA STORAGE ROOMS, STERILITY TEST/GOWN ROOMS AND GENERAL LAB AREAS	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	12	OPERATING PROCEDURE FOR THE DISINFECTION OF MICROBIOLOGY INCUBATORS, MEDIA STORAGE ROOMS, STERILITY TEST/GOWN ROOMS AND GENERAL LAB AREAS	Released
100074074	Ethicon Products,	PREPARATION OF SUPPLIES TO BE STERILIZED	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	4	PREPARATION OF SUPPLIES TO BE STERILIZED	Released
100074077	Ethicon Products, ,	HANDLING AND DISPOSAL OF Viable MICROORGANISMS AND OTHER POTENTIALLY INFECTIOUS WASTE	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	5	HANDLING AND DISPOSAL OF Viable MICROORGANISMS AND OTHER POTENTIALLY INFECTIOUS WASTE	Released
100074077	Ethicon Products, ,	OPERATING PROCEDURE FOR MONITORING TEMPERATURES FOR INCUBATORS, REFRIGERATORS AND MEDIA STORAGE ROOMS	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	12	OPERATING PROCEDURE FOR MONITORING TEMPERATURES FOR INCUBATORS, REFRIGERATORS AND MEDIA STORAGE ROOMS	Released
100074087	Ethicon Products,	OPERATING PROCEDURE FOR LAMINAR FLOW HOODS	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	3	OPERATING PROCEDURE FOR LAMINAR FLOW HOODS	Released
100074087	Ethicon Products, ,	ASSIGNMENT OF STERILIZATION/DECONTAMINATION RUN NUMBERS IN THE MEDIA PREP LAB	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	4	ASSIGNMENT OF STERILIZATION/DECONTAMINATION RUN NUMBERS IN THE MEDIA PREP LAB	Released
100074114	Ethicon Products, ,	PREPARATION OF BROTH MEDIA FOR MICROBIOLOGICAL USE	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	15	PREPARATION OF BROTH MEDIA FOR MICROBIOLOGICAL USE	Released
100074114	Ethicon Products,	PREPARATION OF AGAR MEDIA FOR MICROBIOLOGICAL USE	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	11	PREPARATION OF AGAR MEDIA FOR MICROBIOLOGICAL USE	Released
100074117	Ethicon Products, ,	PREPARATION OF DILUENTS FOR MICROBIOLOGICAL USE	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	11	PREPARATION OF DILUENTS FOR MICROBIOLOGICAL USE	Released
100074117	Ethicon Products,	OMNISPENSE DISPENSER OPERATING PROCEDURE	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	4	OMNISPENSE DISPENSER OPERATING PROCEDURE	Released
100074120	Ethicon Products, J&J Wound Management, ,	Inspection, Maintenance, Calibration and Use of the Viscotek Y-501 IV Viscometer	Work Instruction (Non-PPE)	Quality System	Calibration and Measuring Equipment	6	Inspection, Maintenance, Calibration and Use of the Viscotek Y-501 IV Viscometer	Released
100074120	Ethicon Products, J&J Wound Management, ,	Inspection, Maintenance, Calibration, and Use of the Coulometric Moisture Meters	Work Instruction (Non-PPE)	Quality System	Calibration and Measuring Equipment	2	Inspection, Maintenance, Calibration, and Use of the Coulometric Moisture Meters	Released
100074123	Ethicon Products, ,	WORK INSTRUCTION FOR LABORATORY NOTEBOOK AND DOCUMENTATION REQUIREMENTS	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	11	WORK INSTRUCTION FOR LABORATORY NOTEBOOK AND DOCUMENTATION REQUIREMENTS	Released
100079180	Ethicon-Somerville-WW Quality Compliance	Installation Qualification Protocol for Adaptiv Release 1.2.7	Protocol			1		
100079180	Ethicon-Somerville-WW Quality-NPI/LCM	Installation Qualification Protocol for Adaptiv Release 1.2.7	Protocol			1		
100083206	Ethicon Products, ,	OPERATING PROCEDURE FOR THE ASSIGNMENT OF COPY CONTROL NUMBERS	Work Instruction (Non-PPE)	Quality System	Packaging and Labeling	10	OPERATING PROCEDURE FOR THE ASSIGNMENT OF COPY CONTROL NUMBERS	Released
100083206	Ethicon Products, ,	Operating Procedure for the Completion and Compilation of a Device History Record by Somerville Raw Material Quality Assurance	Work Instruction (Non-PPE)	Quality System	Identification and Traceability	18	Operating Procedure for the Completion and Compilation of a Device History Record by Somerville Raw Material Quality Assurance	Released
100083468	Ethicon-Somerville-WW Quality System	Protocol for ADAPTIV Wave II Deployment for Mentor	Protocol			1		
100083468	Ethicon-Somerville-WW Quality System	Protocol for ADAPTIV Wave II Deployment for Mentor	Protocol			1		
100083540	Ethicon Products, ,	OPERATING PROCEDURE FOR PERFORMING BILL OF MATERIAL MAINTENANCE IN THE JDE ONE WORLD SYSTEM	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	13	OPERATING PROCEDURE FOR PERFORMING BILL OF MATERIAL MAINTENANCE IN THE JDE ONE WORLD SYSTEM	Released
100088997	Ethicon-Somerville Plant-Quality Engineering	Sentinel Preclinical GI Device Characterization	Protocol			1		
100090384	Ethicon-Somerville-Quality Systems and Compliance	STRATAFIX™ Symmetric PDSTM Plus Transit Test # 1873	Protocol			1		

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100092306	Ethicon Products, J&J Wound Management, Women's Health and Urology,	OPERATING PROCEDURE FOR ANNUAL REPORTS TO FDA FOR MEDICAL DEVICES	Procedure (Non-PPE)	Quality System	Management Responsibility	5	OPERATING PROCEDURE FOR ANNUAL REPORTS TO FDA FOR MEDICAL DEVICES	Released
100094111	Ethicon-Somerville-WW Quality System	Procedure for Risk Assessment for Products with a Clinical Use History	Procedure			1		
100095478	Ethicon-Somerville Plant-Quality Assurance Manager	PROCEDURE FOR RECEIPT, STORAGE, AND DISTRIBUTION OF EVICEL AND EVITHROM PRODUCT FOR INTERNAL R&D AND	Procedure			1		
DR-0000004	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Approval of Advertising and Promotional Materials for Medical Devices and Combination Products	Procedure (Non-PPE)	Quality System	Communication	8	na	Released
DR-0000048	Ethicon Products, J&J Wound Management,	Operating Procedure For The Maintenance Of Stability Studies Environmental Chambers	Procedure (Non-PPE)	Quality System	Facilities and Maintenance	7	Operating Procedure For The Maintenance Of Stability Studies Environmental Chambers	Released
DR-0000293	Ethicon Products,	OPERATING PROCEDURE FOR THE APPROVAL OF PRINTING INKS	Work Instruction (Non-PPE)	Quality System	Packaging and Labeling	6	OPERATING PROCEDURE FOR THE APPROVAL OF PRINTING INKS	Released
DR-0000316	Ethicon Products,	OPERATING PROCEDURE FOR DOCUMENT TRANSLATION	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	19	OPERATING PROCEDURE FOR DOCUMENT TRANSLATION	Released
DR-0000384	Ethicon Products,	Operating Procedure for Cycle Counting and Physical Inventory of Raw Material	Work Instruction (Non-PPE)	Quality System	Production	13	Operating Procedure for Cycle Counting and Physical Inventory of Raw Material	Released
FG-0000098	Ethicon Products,	Operating Procedure for Processing Purchase Requisitions and Purchase Orders	Work Instruction (Non-PPE)	Quality System	Procurement	15	Operating Procedure for Processing Purchase Requisitions and Purchase Orders	Released
MS-0000282	Ethicon Products,	OPERATING PROCEDURE FOR THE IMPLEMENTATION OF PURCHASED MATERIAL SPECIFICATIONS WITH SUPPLIERS	Work Instruction (Non-PPE)	Quality System	Procurement	10	OPERATING PROCEDURE FOR THE IMPLEMENTATION OF PURCHASED MATERIAL SPECIFICATIONS WITH SUPPLIERS	Released
MS-0000300	Ethicon Products,	OPERATING PROCEDURE FOR THE IMPLEMENTATION OF DOCUMENTS WITHIN THE ETHICON CHANGE CONTROL SYSTEM FOR THE CORPORATE PURCHASING DEPARTMENT	Work Instruction (Non-PPE)	Quality System	Procurement	9	OPERATING PROCEDURE FOR THE IMPLEMENTATION OF DOCUMENTS WITHIN THE ETHICON CHANGE CONTROL SYSTEM FOR THE CORPORATE PURCHASING DEPARTMENT	Released
MS-0000345	Ethicon Products,	OPERATING PROCEDURE FOR THE TRANSFER OF BULK RAW MATERIALS FROM THE SOMERVILLE WAREHOUSE TO ALL DOMESTIC PLANT LOCATIONS	Work Instruction (Non-PPE)	Quality System	Distribution Handling and Storage	8	OPERATING PROCEDURE FOR THE TRANSFER OF BULK RAW MATERIALS FROM THE SOMERVILLE WAREHOUSE TO ALL DOMESTIC PLANT LOCATIONS	Released
MS-0000681	Ethicon Products, J&J Wound Management,	OPERATING PROCEDURE FOR FREIGHT CARRIER SELECTION	Work Instruction (Non-PPE)	Quality System	Distribution Handling and Storage	4	OPERATING PROCEDURE FOR FREIGHT CARRIER SELECTION	Released
MS201-001	Ethicon Products, J&J Wound Management,	Litigation Support Practices	Procedure (Non-PPE)	Quality System	Complaints, Vigilance, Recalls	3	Litigation Support Practices	Released
MS207-012	Ethicon Products,	Operating Procedure For The Control and Disposition of Nonconforming Materials and Nonconformance Processing	Work Instruction (Non-PPE)	Quality System	Non-Conformity	43	Operating Procedure For The Control and Disposition of Nonconforming Materials and Nonconformance Processing	Released
MS207-018	Ethicon Products,	Company Policy for the ETHICON Instrument Calibration Program	Policy	Quality System	Calibration and Measuring Equipment	1	Company Policy for the ETHICON Instrument Calibration Program	Released
MWI-0000042	Ethicon Products,	Company Policy for the ETHICON Preventive Maintenance Program	Policy	Quality System	Calibration and Measuring Equipment	1	Company Policy for the ETHICON Preventive Maintenance Program	Released
MWI-0000043	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Style Guide and Templates for ETHICON Text Documents	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	32 (33)	Style Guide and Templates for ETHICON Text Documents	Released
MWI-0000044	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Company Procedure Defining Document Linkage to the Quality Manual for ETHICON, North America	Procedure (Non-PPE)	Quality System	All Quality System Processes	15 (16)	Company Procedure Defining Document Linkage to the Quality Manual for ETHICON, North America	Released
NB-0156	Ethicon Products,	Process Specification for Servicing Repairable Devices	Procedure (Non-PPE)	Quality System	Servicing	6	Process Specification for Servicing Repairable Devices	Released
NS-1809	Ethicon Products,	Company Procedure for the Redress and Relabel of Externally Manufactured Products	Procedure (Non-PPE)	Quality System	Packaging and Labeling	1	Company Procedure for the Redress and Relabel of Externally Manufactured Products	Released
OP204-011	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Preparation and Approval Process for Protocols, Amendments, and Administrative Changes for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	9	Procedure for Preparation and Approval Process for Protocols, Amendments, and Administrative Changes for Clinical Trials	Released
OP204-015	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR PREPARATION, REVIEW, AND APPROVAL OF CASE REPORT FORMS FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	na	Released
OP210-004	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR PREPARATION, REVIEW, AND APPROVAL OF INFORMED CONSENT DOCUMENTS FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
OP252-002	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR THE SITE EVALUATION VISIT FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	7	Procedure for the Site Evaluation Visit for Clinical Trials	Released

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OP252-002	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR THE SITE INITIATION VISIT FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	8	Procedure for the Site Initiation Visit for Clinical Trials	Released
OP600-005	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR THE SITE MONITORING VISIT FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	8	Procedure for the Site Monitoring Visit for Clinical Trials	Released
OP600-011	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR THE SITE CLOSE OUT FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	7	Procedure for the Site Close Out for Clinical Trials	Released
OP600-011	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Procedure for Preparation, Review and Approval of the Investigator's Brochure for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	3	na	Released
OP600-011	Ethicon-Somerville Plant-Quality Systems and Compliance	OPERATING PROCEDURE FOR QUARTERLY ETHYLENE OXIDE BIOPURDEN AUDIT PROGRAM	Procedure			67		
OP600-020	Ethicon-Somerville-Quality Systems and Compliance	OPERATING PROCEDURE FOR THE QUARTERLY PARTICULATE COUNT AUDIT CONDUCTED INSIDE THE CONTROLLED MANUFACTURING ENVIRONMENT (ENVIRONMENT CONTROL LEVEL #2) AND MICROBIOLOGY DEPARTMENT	Procedure			45		
OP600-026	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR PREPARING CLINICAL STUDY REPORTS FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	na	Released
OP600-062	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Procedure for Suspicion of Misrepresentation and Misconduct for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	3	na	Released
OP600-073	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Procedure for Oracle Clinical System Security and Disaster Recovery for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	5	Procedure for Oracle Clinical System Security and Disaster Recovery for Clinical Trials	Released
OP600-074	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Clinical Development Procedure for Creation and Maintenance of the Global Library for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	3	Clinical Development Procedure for Creation and Maintenance of the Global Library for Clinical Trials	Released
OP600-085	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR STATISTICAL INPUT INTO CLINICAL INVESTIGATION PLANS/PROTOCOLS FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
OP600-087	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Procedure for the Creation of an Annotated Case Report Form for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	5	Procedure for the Creation of an Annotated Case Report Form for Clinical Trials	Released
OP600-105	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Procedure for Randomization and Blinding for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	3	Procedure for Randomization and Blinding for Clinical Trials	Released
OP601-005	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS PROCEDURE FOR A DATA MANAGEMENT PLAN FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	5	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS PROCEDURE FOR A DATA MANAGEMENT PLAN FOR CLINICAL TRIALS	Released
OP601-007	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CLINICAL DEVELOPMENT PROCEDURE FOR DATA ENTRY IN A CLINICAL DATA MANAGEMENT SYSTEM (CDMS)	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	CLINICAL DEVELOPMENT PROCEDURE FOR DATA ENTRY IN A CLINICAL DATA MANAGEMENT SYSTEM (CDMS)	Released
OP601-009	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Clinical Development Procedure for the Database Quality Control Process for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	CLINICAL DEVELOPMENT PROCEDURE FOR THE DATABASE QUALITY CONTROL PROCESS FOR CLINICAL TRIALS	Released
OP603-036	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR THE STATISTICAL ANALYSIS PLAN FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	3	na	Released
OP603-097	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR LOCKING AND UNLOCKING OF A DATABASE FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	5	Procedure for Locking and Unlocking of a Database for Clinical Trials	Released
OP603-124	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR DATA EXTRACTION FROM THE CLINICAL TRIAL DATABASE	Procedure (Non-PPE)	Quality System	All Quality System Processes	5	Procedure for Data Extraction from the Clinical Trial Database	Released
OP603-180	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR REPORTING STATISTICAL RESULTS FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
OP603-334	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Clinical Development and Medical Affairs Procedure for Creation and Testing of a Database for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	Clinical Development and Medical Affairs Procedure for Creation and Testing of a Database for Clinical Trials	Released
OP606-047	Ethicon-Somerville-Quality Systems and Compliance	OPERATING PROCEDURE FOR THE PROCESSING OF SPECIALTY ITEMS AT ETHICON, INC., CORNELIA, GEORGIA	Procedure			16		

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OP607-052	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR INTERIM AND FOLLOW-UP ANALYSES FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
OP611-079	Ethicon Products, ,	Company Procedure for Raw Material Testing (RMT) Training Requirements	Procedure (Non-PPE)	Quality System	Training	4	Company Procedure for Raw Material Testing (RMT) Training Requirements	Released
OP611-104	Ethicon Products, ,	Procedure for documentation for Japan PAL	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	2	Procedure for documentation for Japan PAL	Released
OP611-140	Ethicon Products, J&J Wound Management, ,	Company Procedure for Management of Litigation Support Procedures for Product Liability	Procedure (Non-PPE)	Quality System	Complaints, Vigilance, Recalls	5	Company Procedure for Management of Litigation Support Procedures for Product Liability	Released
OP612-017	Ethicon Products, J&J Wound Management, Women's Health and Urology, ,	PROCEDURE FOR MEDICAL DATA CODING OF TERMS WITHIN A CLINICAL TRIAL TO A STANDARDIZED DICTIONARY	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	na	Released
OP612-019	Ethicon Products, ,	Procedure for archiving product packaging samples	Procedure (Non-PPE)	Quality System	Packaging and Labeling	2	Procedure for archiving product packaging samples	Released
OP613-002	Ethicon Products, ,	Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Material for Medical Devices	Procedure (Non-PPE)	Quality System	Management Responsibility	2	Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Material for Medical Devices	Released
OP613-004	Ethicon Products, ,	Company Procedure for Weekly Review of JDE Account Activity	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	2	Company Procedure for Weekly Review of JDE Account Activity	Released
OP650-011	Ethicon Products, J&J Wound Management, Women's Health and Urology, ,	COMPANY PROCEDURE: GLOSSARY OF CLINICAL DEFINITIONS	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	na	Released
OP650-011	Ethicon-Somerville-WW Quality System	Operating Procedure for Design Failure Modes and Effects Analysis	Procedure			14		
OP653-011	Ethicon Products, ,	COMPANY PROCEDURE FOR RESPONDING TO AND REPORTING SECURITY INCIDENTS	Procedure (Non-PPE)	Quality System	Facilities and Maintenance	2	COMPANY PROCEDURE FOR RESPONDING TO AND REPORTING SECURITY INCIDENTS	Released
OP653-011	Ethicon-Somerville-WW Quality System	Litigation Support Practices	Procedure			3		
OP653-014	Ethicon Products, J&J Wound Management, Women's Health and Urology, ,	COMPANY PROCEDURE FOR THE LIMITED RELEASE OF SPECIAL ORDER DEVICES	Procedure (Non-PPE)	Quality System	Planning	1 (2)	COMPANY PROCEDURE FOR THE LIMITED RELEASE OF SPECIAL ORDER DEVICES	Released
PKDWG-0000303	Women's Health and Urology, ,	Company Procedure for Servicing Ethicon, Inc. Repairable Products	Procedure (Non-PPE)	Quality System	Servicing	1	Company Procedure for Servicing Ethicon, Inc. Repairable Products	Released
PKDWG-0000304	Ethicon Products, ,	Company Procedure for the ETHICON Instrument Calibration Program	Procedure (Non-PPE)	Quality System	Calibration and Measuring Equipment	4	Company Procedure for the ETHICON Instrument Calibration Program	Released
PL-0000012	Ethicon Products, ,	Company Procedure for the ETHICON Preventive Maintenance Program	Procedure (Non-PPE)	Quality System	Facilities and Maintenance	2	Company Procedure for the ETHICON Preventive Maintenance Program	Released
PL-0000015	Ethicon Products, J&J Wound Management, Women's Health and Urology, ,	Company Procedure for a Sterilization Strategy/Justification	Procedure (Non-PPE)	Quality System	Sterilization and Microbiology	1	Company Procedure for a Sterilization Strategy/Justification	Released
PL-0000023	Ethicon Products, J&J Wound Management, Women's Health and Urology, ,	Company Procedure for Demand Planning for ETHICON Inc	Procedure (Non-PPE)	Quality System	Planning	1	Company Procedure for Demand Planning for ETHICON Inc	Released
PL-0000024	Ethicon Products, J&J Wound Management, Women's Health and Urology, ,	Company Procedure for Supply Planning Governance Process for ETHICON Inc	Procedure (Non-PPE)	Quality System	Planning	1	Company Procedure for Supply Planning Governance Process for ETHICON Inc	Released
PL-0000086	Ethicon Products, J&J Wound Management, Women's Health and Urology, ,	Company Procedure for Inventory Management Process for ETHICON Inc	Procedure (Non-PPE)	Quality System	Planning	1	Company Procedure for Inventory Management Process for ETHICON Inc	Released
PR-0000002	Ethicon Products, ,	GSC Procedure For the Periodic Review of EXCEL Spread Sheets and Applied Security	Procedure (Non-PPE)	Quality System	Planning	1	GSC Procedure For the Periodic Review of EXCEL Spread Sheets and Applied Security	Released
PR-0000002	Ethicon-Somerville-WW Quality System	Style Guide and Templates for ETHICON Text Documents	Procedure			30		
PR-0000002	Ethicon-Somerville-WW Quality System	Style Guide and Templates for ETHICON Text Documents	Procedure			30		
PR-0000006	Ethicon Products, J&J Wound Management, Women's Health and Urology, ,	Procedure for Work Instructions for QAU-GLP Responsibilities	Procedure (Non-PPE)	Quality System	Compliance	1	Procedure for Work Instructions for QAU-GLP Responsibilities	Released
PR-0000009	Ethicon-Somerville-WW Quality System	Company Procedure Defining Document Linkage to the Quality Manual for ETHICON, North America	Procedure			14		
PR-0000009	Ethicon-Somerville-WW Quality System	Company Procedure Defining Document Linkage to the Quality Manual for ETHICON, North America	Procedure			14		
PR-0000112	Ethicon Products, ,	Procedure on Monthly review of Invalid Login attempts to JDE	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	1	Procedure on Monthly review of Invalid Login attempts to JDE.	Released
PR-0000114		COMPANY PROCEDURE FOR CUSTOMER COMPLAINT CATEGORY MODIFICATIONS	Procedure (Non-PPE)			4		
PR-0000118		FRANCHISE PROCEDURE FOR PRODUCT COMPLAINT MANAGEMENT	Procedure (Non-PPE)			20		
PR-0000119		COMPANY PROCEDURE FOR GLOBAL CUSTOMER COMPLAINT CATEGORY MODIFICATIONS	Procedure (Non-PPE)			5		

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PR-0000172	Ethicon Products,	Company Procedure for User Maintenance of the LabManager LIMS System	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	1	Company Procedure for User Maintenance of the LabManager LIMS System	Released
PR-0000173	Ethicon Products,	Administration of Test Method Documents Controlled within the Somerville New Jersey Performance Evaluation Group	Procedure (Non-PPE)	Quality System	Quality System	1	Administration of Test Method Documents Controlled within the Somerville New Jersey Performance Evaluation Group	Released
PR-0000173	Ethicon Products,	COMPANY PROCEDURE FOR CREATION OF GLOBAL TRADE IDENTIFICATION NUMBERS (GTINS) IN THE MASTER DATA MANAGEMENT (MDM) SYSTEM	Procedure (Non-PPE)	Quality System	Identification and Traceability	1	COMPANY PROCEDURE FOR CREATION OF GLOBAL TRADE IDENTIFICATION NUMBERS (GTINS) IN THE MASTER DATA MANAGEMENT (MDM) SYSTEM	Released
PR-0000174	Ethicon Products,	COMPANY PROCEDURE FOR PLANNING HOLDS	Procedure (Non-PPE)	Quality System	Production	1	COMPANY PROCEDURE FOR PLANNING HOLDS	Released
PR-0000174	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Change Management Process in the ADAPTIV System	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	na	Released
PR-0000175	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Managing Part Masters and Part Plants in ADAPTIV	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	3	na	Released
PR-0000176	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Managing Bills of Materials and Device Master Records in ADAPTIV	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	5	na	Released
PR-0000176	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Managing ERP Transactions and Flat Files in ADAPTIV	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	2	na	Released
PR-0000177	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Managing Main Part in ADAPTIV	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	3	na	Released
PR-0000177	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Document Management Process in the ADAPTIV System	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	4 (5)	na	Released
PR-0000178	Ethicon Products, J&J Wound Management, Women's Health and Urology,	ADAPTIV Change Analyst Process	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	3	na	Released
PR-0000178	Ethicon Products, J&J Wound Management, Women's Health and Urology,	MDD ADAPTIV Mass Replace BOM (Bill of Material) Component Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
PR-0000179	Ethicon Products, J&J Wound Management, Women's Health and Urology,	MDD ADAPTIV Product Configuration Change Management Procedure	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	2	na	Released
PR-0000179	Ethicon Products, J&J Wound Management, Women's Health and Urology,	MDD ADAPTIV ERP (Enterprise Resource Planning) Transactions and Flat Files Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
PR-0000180	Ethicon Products, J&J Wound Management, Women's Health and Urology,	MDD ADAPTIV Part Routing Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
PR-0000180	Ethicon Products, J&J Wound Management, Women's Health and Urology,	MDD ADAPTIV Work Center Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
PR-0000181	Ethicon Products, J&J Wound Management, Women's Health and Urology,	MDD ADAPTIV Effectivity Management and Material Disposition Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
PR-0000181	Ethicon Products, J&J Wound Management, Women's Health and Urology,	MDD ADAPTIV DMR (Device Master Record) Parent and Child Release Level Alignment Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
PR-0000182	Ethicon Products, J&J Wound Management, Women's Health and Urology,	MDD ADAPTIV Creating a Branch BOM/DMR (Bill of Material/Device Master Record) Structure Procedure	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
PR-0000182	Ethicon Products, J&J Wound Management, Women's Health and Urology,	MDD ADAPTIV Cross Franchise Shared Parts Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
PR-0000183	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Global Discontinue Part Process	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	4	na	Released
PR-0000183	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Global FG Product Manufactured Creation Process	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	4	na	Released
PR-0000184	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Global FG Product External Creation Process	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	3	na	Released

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PR-0000184	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Right Product/Right Country Process	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	5	na	Released
PR-0000185	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Global Product Maintenance and Change Process	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	5	na	Released
PR-0000185	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Enterprise Resource Planning (ERP) Transactions and Flat Files Work Instruction	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	na	Released
PR-0000186	Ethicon Products,	GUIDELINES FOR TRANSFER OF INTERNATIONAL AFFILIATE MATERIALS	Procedure (Non-PPE)	Quality System	Identification and Traceability	7	GUIDELINES FOR TRANSFER OF INTERNATIONAL AFFILIATE MATERIALS	Released
PR-0000186	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Company Procedure for Process Change Control for Externally Manufactured Products	Procedure (Non-PPE)	Quality System	Compliance	10	Company Procedure for Process Change Control for Externally Manufactured Products	Released
PR-0000187	Ethicon Products,	Procedure for batch, lot, or serial number coding and traceability of externally manufactured finished goods	Procedure (Non-PPE)	Quality System	Compliance	3	Procedure for batch, lot, or serial number coding and traceability of externally manufactured finished goods	Released
PR-0000187	Ethicon Products,	WORK INSTRUCTIONS FOR LABELING OF FACILITY PIPING	Procedure (Non-PPE)	Quality System	Facilities and Maintenance	3	WORK INSTRUCTIONS FOR LABELING OF FACILITY PIPING	Released
PR-0000188	Ethicon Products,	WORK INSTRUCTIONS FOR CONTROL AND UPDATING OF FACILITY DRAWINGS (UTILITY DISTRIBUTION PIPING)	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	3	WORK INSTRUCTIONS FOR CONTROL AND UPDATING OF FACILITY DRAWINGS (UTILITY DISTRIBUTION PIPING)	Released
PR-0000188	Ethicon Products,	Company Procedure for Equipment Electrical standards	Procedure (Non-PPE)	Quality System	Facilities and Maintenance	3	Company Procedure for Equipment Electrical standards	Released
PR-0000189	Women's Health and Urology,	Company Procedure for Developing Capital Equipment Service Bulletins for Ethicon Repair Facilities	Procedure (Non-PPE)	Quality System	Servicing	5	Company Procedure for Developing Capital Equipment Service Bulletins for Ethicon Repair Facilities	Released
PR-0000190	Ethicon Products, J&J Wound Management,	Work Instructions for Equipment and Process Control Procedure	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	24 (25)	Work Instructions for Equipment and Process Control Procedure	Released
PR-0000190	Ethicon Products,	Work instructions for Gynecare research & development training requirements	Work Instruction (Non-PPE)	Quality System	Training	2	Work instructions for Gynecare research & development training requirements	Released
PR-0000191	Ethicon Products,	WORK INSTRUCTIONS FOR MAXIMO AND PILGRIM PREVENTATIVE MAINTENANCE	Procedure (Non-PPE)	Quality System	Calibration and Measuring Equipment	3	WORK INSTRUCTIONS FOR MAXIMO AND PILGRIM PREVENTATIVE MAINTENANCE	Released
PR-0000192	Ethicon Products,	Company Procedure for Destruction of Materials	Procedure (Non-PPE)	Quality System	Identification and Traceability	24	Company Procedure for Destruction of Materials	Released
PR-0000192	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR MANAGEMENT OF FINISHED GOODS MINIMUM SHIPPING AND RECEIVING SHELF LIFE PARAMETERS	Procedure (Non-PPE)	Quality System	Identification and Traceability	13	PROCEDURE FOR MANAGEMENT OF FINISHED GOODS MINIMUM SHIPPING AND RECEIVING SHELF LIFE PARAMETERS	Released
PR-0000193	Ethicon Products,	PROJECT RELATED SHOP-FLOOR PRODUCTION ORDER REQUESTS	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	13	PROJECT RELATED SHOP-FLOOR PRODUCTION ORDER REQUESTS	Released
PR-0000193	Ethicon Products,	COMPANY PROCEDURE FOR SALES & OPERATIONS PLANNING	Procedure (Non-PPE)	Quality System	Planning	4	COMPANY PROCEDURE FOR SALES & OPERATIONS PLANNING	Released
PR-0000194	Ethicon Products,	WORK INSTRUCTIONS FOR SUPPLIER CERTIFICATES OF INSURANCE AND LETTERS OF INDEMNITY	Work Instruction (Non-PPE)	Quality System	Procurement	4	WORK INSTRUCTIONS FOR SUPPLIER CERTIFICATES OF INSURANCE AND LETTERS OF INDEMNITY	Released
PR-0000194	Ethicon Products,	WORK INSTRUCTIONS FOR OBTAINING SECRECY AGREEMENTS OR STANDARD DEVELOPMENT CONTRACTS WITH SUPPLIERS	Work Instruction (Non-PPE)	Quality System	Procurement	4	WORK INSTRUCTIONS FOR OBTAINING SECRECY AGREEMENTS OR STANDARD DEVELOPMENT CONTRACTS WITH SUPPLIERS	Released
PR-0000195	Ethicon Products,	Procurement Policy for the Solicitation of Competitive Bids & Contract Development	Procedure (Non-PPE)	Quality System	Procurement	11	Procurement Policy for the Solicitation of Competitive Bids & Contract Development	Released
PR-0000195	Ethicon Products,	Work Instruction for Emergency PO	Work Instruction (Non-PPE)	Quality System	Procurement	2	Work Instruction for Emergency PO	Released
PR-0000196	Ethicon Products,	Work Instructions for Handling Product Complaints	Work Instruction (Non-PPE)	Quality System	Complaints, Vigilance, Recalls	44	Work Instructions for Handling Product Complaints	Released
PR-0000196	Ethicon Products,	Work Instructions for DMS Users	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	7	Work Instructions for DMS Users	Released
PR-0000197	Ethicon Products,	PROCEDURE FOR PROCESSING NEW RAW MATERIAL CODES AND LOADING CODES TO INVENTORY SYSTEM(S)	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	26	PROCEDURE FOR PROCESSING NEW RAW MATERIAL CODES AND LOADING CODES TO INVENTORY SYSTEM(S)	Released
PR-0000197	Ethicon Products,	PROCEDURE FOR RELEASE OF NONSALEABLE PRODUCTS OR MATERIALS	Procedure (Non-PPE)	Quality System	Identification and Traceability	23	PROCEDURE FOR RELEASE OF NONSALEABLE PRODUCTS OR MATERIALS	Released
PR-0000198	Ethicon Products,	Company Procedure for the Control of Nonsaleable, Developmental Products and Materials Which Are Not Intended For Human or Animal Use	Procedure (Non-PPE)	Quality System	Identification and Traceability	9	Company Procedure for the Control of Nonsaleable, Developmental Products and Materials Which Are Not Intended For Human or Animal Use	Released
PR-0000198	Ethicon Products,	Procedure for the sterilization of nonsaleable products or materials	Procedure (Non-PPE)	Quality System	Identification and Traceability	6	Procedure for the sterilization of nonsaleable products or materials	Released
PR-0000199	Women's Health and Urology,	Company Procedure for Processing Ethicon, Inc. Repairable Products	Procedure (Non-PPE)	Quality System	Servicing	6	Company Procedure for Processing Ethicon, Inc. Repairable Products	Released
PR-0000199	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Company Procedures for Decontamination of Product Complaint Samples	Procedure (Non-PPE)	Quality System	Complaints, Vigilance, Recalls	18	Company Procedures for Decontamination of Product Complaint Samples	Released

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PR-0000200	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR DETERMINING EXPIRY DATE PERIODS AND STORAGE CONDITIONS	Procedure (Non-PPE)	Quality System	Identification and Traceability	8	PROCEDURE FOR DETERMINING EXPIRY DATE PERIODS (shelf life) and associated storage conditions/requirements based on stability study results	Released
PR-0000201	Ethicon Products,	STATISTICAL TECHNIQUES PROCEDURE	Procedure (Non-PPE)	Quality System	Statistical Techniques	9	STATISTICAL TECHNIQUES PROCEDURE	Released
PR-0000201	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR PACKAGE DEVELOPMENT	Procedure (Non-PPE)	Quality System	Packaging and Labeling	11	PROCEDURE FOR PACKAGE DEVELOPMENT	Released
PR-0000202	Ethicon Products,	Company Procedure for CPAS Application Administration	Procedure (Non-PPE)	Quality System	Corrective and Preventive Actions	7	Company Procedure for CPAS Application Administration	Released
PR-0000202	Ethicon Products,	Work Instructions for GLP Abbreviations/Standard Terminology	Work Instruction (Non-PPE)	Quality System	Compliance	3	Work Instructions for GLP Abbreviations/Standard Terminology	Released
PR-0000203	Ethicon Products,	Work Instructions for the GLP Master Schedule	Work Instruction (Non-PPE)	Quality System	Compliance	3	Work Instructions for the GLP Master Schedule	Released
PR-0000203	Ethicon Products,	Work Instructions for GLP Regulatory Compliance Inspection Reporting	Work Instruction (Non-PPE)	Quality System	Compliance	4	Work Instructions for GLP Regulatory Compliance Inspection Reporting	Released
PR-0000204		FRANCHISE PROCEDURE FOR ADVERSE EVENT REPORTING FOR JAPAN PAL REQUIREMENTS	Procedure (Non-PPE)			5		
PR-0000212	Ethicon Products,	Work Instructions for GLP Training Records	Work Instruction (Non-PPE)	Quality System	Training	2	Work Instructions for GLP Training Records	Released
PR-0000213	Ethicon Products,	Work Instructions for the Inspection, Classification and Monitoring of Contract Research Organizations (CRO)	Work Instruction (Non-PPE)	Quality System	Compliance	5	Work Instructions for the Inspection, Classification and Monitoring of Contract Research Organizations (CRO)	Released
PR-0000214	Ethicon Products,	Work Instructions for the Preparation of a GLP QA Statement	Work Instruction (Non-PPE)	Quality System	Compliance	2	Work Instructions for the Preparation of a GLP QA Statement	Released
PR-0000222	Ethicon Products,	Lab 2000 R&D LIMS System Administration Procedure for Implementing New Login Templates	Work Instruction (Non-PPE)	Quality System	Production	2	Lab 2000 R&D LIMS System Administration Procedure for Implementing New Login Templates	Released
PR-0000232	Ethicon Products,	PR800-022 - Lab 2000 R&D LIMS System Administration Procedure for Resetting User Passwords	Work Instruction (Non-PPE)	Quality System	Design and Development	2	PR800-022 - Lab 2000 R&D LIMS System Administration Procedure for Resetting User Passwords	Released
PR-0000232	Ethicon-Somerville-WW Quality System	Company Procedure for Management of Litigation Support Procedures for Product Liability	Procedure			5		
PR-0000250	Ethicon Products,	PR800-023 - Lab 2000 R&D LIMS System Administration Procedure for Implementing New Test Methods	Work Instruction (Non-PPE)	Quality System	Design and Development	2	PR800-023 - Lab 2000 R&D LIMS System Administration Procedure for Implementing New Test Methods	Released
PR-0000252	Ethicon Products,	PR800-027 - Lab 2000 R&D LIMS System Administration Procedure for Adding and Removing Users	Work Instruction (Non-PPE)	Quality System	Design and Development	2	PR800-027 - Lab 2000 R&D LIMS System Administration Procedure for Adding and Removing Users	Released
PR-0000252	Ethicon Products,	Company Procedure for Materials Tracing	Procedure (Non-PPE)	Quality System	Identification and Traceability	17	Company Procedure for Materials Tracing	Released
PR-0000253	Ethicon Products,	WORK INSTRUCTIONS FOR RECEIPT OF RETURNED RAW MATERIAL TO CORNELIA	Work Instruction (Non-PPE)	Quality System	Distribution Handling and Storage	3	WORK INSTRUCTIONS FOR RECEIPT OF RETURNED RAW MATERIAL TO CORNELIA	Released
PR-0000255	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Process Specification for the ETHICON Change Control System Business Administration Process	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	9	Process Specification for the ETHICON Change Control System Business Administration Process	Released
PR-0000269	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Process Specification for the Paper-Based Document Management Process	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	5	Process Specification for the Paper-Based Document Management Process	Released
PR-0000271	Ethicon Products,	Process Specification for the Product Release Authorization (PRA) Process	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	11	Process Specification for the Product Release Authorization (PRA) Process	Released
PR-0000271	Ethicon Products, J&J Wound Management,	ETHICON Change Control System System Administrator Manual	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	3	ETHICON Change Control System System Administrator Manual	Released
PR-0000280	Ethicon Products,	Process Specification for Creation and Revision of Needle Specifications, Needle Blanks and Needle Templates	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	5	Process Specification for Creation and Revision of Needle Specifications, Needle Blanks and Needle Templates	Released
PR-0000301	Ethicon Products,	Process Specification for ETHICON Engineering Drawing and Equipment Bills of Material Standards	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	5	Process Specification for ETHICON Engineering Drawing and Equipment Bills of Material Standards	Released
PR-0000303	Ethicon Products,	Process Specification for Creation of Finished Goods Specifications and Release of Sterile Product Produced by External Manufacturers	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	7	Process Specification for Creation of Finished Goods Specifications and Release of Sterile Product Produced by External Manufacturers	Released
PR-0000321	Ethicon Products, Women's Health and Urology,	Trending Capital Equipment Product Complaints	Work Instruction (Non-PPE)	Quality System	Servicing	5	Trending Capital Equipment Product Complaints	Released
PR-0000322	Ethicon Products,	Process Specification for JDE OneWorld Backorder Release	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specification for JDE OneWorld Backorder Release	Released
PR-0000330	Ethicon Products,	Process Specification for JDE OneWorld Distribution Inquiries	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specification for JDE OneWorld Distribution Inquiries	Released
PR-0000343		Franchise procedure for the addition, modification, or deletion of Remetrex assignment triggers or trigger plans	Procedure (Non-PPE)			1		

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PR-0000364	Ethicon Products,	Process Specification for JDE OneWorld Distribution Reports	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specification for JDE OneWorld Distribution Reports	Released
PR-0000378	Ethicon Products,	Process Specification for JDE OneWorld Enter and Process JDE COACT Transfer Order	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specification for JDE OneWorld Enter and Process JDE COACT Transfer Order	Released
PR-0000379	Ethicon Products,	Process Specification for JDE OneWorld Enter and Process QA to QA Transfer Order	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specification for JDE OneWorld Enter and Process QA to QA Transfer Order	Released
PR-0000380	Ethicon Products,	Process Specification for JDE OneWorld Work Order Cancellation	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Work Order Cancellation	Released
PR-0000381	Ethicon Products,	Process Specification for JDE OneWorld Work Order Status Update	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Work Order Status Update	Released
PR-0000382	Ethicon Products,	Process Specification for JDE OneWorld Unpick Unpack Sales Orders	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specification for JDE OneWorld Unpick Unpack Sales Orders	Released
PR-0000382	Ethicon-Somerville-WW Quality System	Procedure for Work Instructions for QAU-GLP Responsibilities	Procedure			1		
PR-0000385		Franchise Procedure For Post Market Surveillance	Procedure (Non-PPE)			5		
PR-0000393	Ethicon Products,	Process Specification for JDE OneWorld Transfer Orders	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Transfer Orders	Released
PR-0000525	Ethicon Products,	Process Specification for JDE OneWorld Trace/Track Lots	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Trace/Track Lots	Released
PR-0000527	Ethicon Products,	Process Specification for JDE OneWorld Shop Floor Control Reports	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Shop Floor Control Reports	Released
PR-0000528	Ethicon Products,	Process Specification for JDE OneWorld Shop Floor Control Inquiries	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Shop Floor Control Inquiries	Released
PR-0000529	Ethicon Products,	Process Specification for JDE OneWorld Sales Order Processing	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specification for JDE OneWorld Sales Order Processing	Released
PR-0000530	Ethicon Products,	Process Specification for JDE OneWorld Recommit Future Orders	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specification for JDE OneWorld Recommit Future Orders	Released
PR-0000542	Ethicon Products,	Process Specification for JDE OneWorld Reclassification	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Reclassification	Released
PR-0000558	Ethicon Products,	Process Specification for JDE OneWorld Receipt Routing	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specification for JDE OneWorld Receipt Routing	Released
PR-0000564		Franchise Procedure for the Global Harms List	Procedure (Non-PPE)			3		
PR-0000587	Ethicon Products,	Process Specification for JDE OneWorld Purchase Order Receipts	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Purchase Order Receipts	Released
PR-0000593		FRANCHISE PROCEDURE FOR ANVISA TECHNOVIGILANCE REPORTING REQUIREMENTS	Procedure (Non-PPE)			1		
PR-0000608	Ethicon Products,	Process Specification for JDE OneWorld Product Data Management Inquiries	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Product Data Management Inquiries	Released
PR-0000629	Ethicon Products,	Process Specification for JDE OneWorld Product Data Management Reports	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Product Data Management Reports	Released
PR-0000639	Ethicon Products,	Process Specification for JDE OneWorld Processing Credit Orders Manually	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specification for JDE OneWorld Processing Credit Orders Manually	Released
PR-0000639	Ethicon-Somerville-Quality Systems and Compliance	Administration of Test Method Documents Controlled within the Somerville New Jersey Performance Evaluation Group	Procedure			1		
PR-0000646	Ethicon Products,	Process Specification for JDE OneWorld Process VMI Transaction from PO to Ethicon Ownership	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specification for JDE OneWorld Process VMI Transaction from PO to Ethicon Ownership	Released
PR-0000647	Ethicon Products,	Process Specification for JDE OneWorld Physical Inventory	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Physical Inventory	Released
PR-0000649	Ethicon-Somerville-WW Quality System	FRANCHISE PROCEDURE FOR ADOBE ACROBAT DIGITAL SIGNATURE	Procedure			1		
PR-0000649	Ethicon-Somerville-WW Quality System	FRANCHISE PROCEDURE FOR ADOBE ACROBAT DIGITAL SIGNATURE	Procedure			1		
PR-0011356	Compliance	Management Review (SOP 1-02)	Procedure (Non-PPE)			1		
PR-0011359	Ethicon Products,	Process Specification for JDE OneWorld Parts List and Routing Modificaiton	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Parts List and Routing Modificaiton	Released
PR-0011361	Ethicon Products,	Process Specification for JDE OneWorld Lot Status Changes	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Lot Status Changes	Released
PR-0011362	Ethicon Products,	Process Specification for JDE OneWorld Lot Number Assignment and Expiration Dating	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Lot Number Assignment and Expiration Dating	Released
PR-0011363	Ethicon Products,	Process Specification for JDE OneWorld Kanbans	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specification for JDE OneWorld Kanbans	Released
PR-0011364	Ethicon Products,	Process Specification for JDE OneWorld Inventory Counting Adjustments	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Inventory Counting Adjustments	Released
PR-0011365	Ethicon Products,	Process Specification for JDE OneWorld Inventory Transfer	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Inventory Transfer	Released
PR-0011367	Ethicon Products,	Process Specification for JDE OneWorld Inventory Management Reports	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Inventory Management Reports	Released
PR-0011371	Ethicon Products,	Process Specification for JDE OneWorld Inventory Management Inquiries	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Inventory Management Inquiries	Released

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PR-0011393	Ethicon Products,	Process Specification for JDE OneWorld Inventory Issues - Sales/Marketing, R&D, QA	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Inventory Issues - Sales/Marketing, R&D, QA	Released
PR-0011395	Ethicon Products,	Process Specification for JDE OneWorld Destruction of Inventory	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Destruction of Inventory	Released
PR-0011410	Ethicon Products,	Process Specification for JDE OneWorld Cycle Count	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Cycle Count	Released
PR-0011411	Ethicon Products,	Process Specification for JDE OneWorld Consignment and Mixed Order Processing	Work Instruction (Non-PPE)	Quality System	Planning	3	Process Specification for JDE OneWorld Consignment and Mixed Order Processing	Released
PR-0011417	Ethicon Products,	Process Specification for Onsite paper and electronic record cleanout.	Procedure (Non-PPE)	Quality System	Record Management	16	Process Specification for Onsite paper and electronic record cleanout.	Released
PR-0011418	Ethicon Products,	Process Specification for Tracking Corrections in CPAS	Work Instruction (Non-PPE)	Quality System	Corrective and Preventive Actions	9	Process Specification for Tracking Corrections in CPAS	Released
PR-0011421	Ethicon Products,	Process Specification to Create/Delete/Modify Routes in MES	Work Instruction (Non-PPE)	Quality System	Production	2	Process Specification to Create/Delete/Modify Routes in MES	Released
PR-0011423	Ethicon Products,	Process Specification for Creation and Maintenance of Work Centers in MES and JDE OneWorld	Work Instruction (Non-PPE)	Quality System	Production	2	Process Specification for Creation and Maintenance of Work Centers in MES and JDE OneWorld	Released
PR-0011424	Ethicon Products,	Process Specification for Creation and Maintenance of Standard Operations in MES and JDE OneWorld	Work Instruction (Non-PPE)	Quality System	Production	1	Process Specification for Creation and Maintenance of Standard Operations in MES and JDE OneWorld	Released
PR-0011444	Ethicon Products,	Export, Import and Merge of Datasweep Objects and Configuration Files in Datasweep Advantage Manufacturing Execution System	Work Instruction (Non-PPE)	Quality System	Production	3	Export, Import and Merge of Datasweep Objects and Configuration Files in Datasweep Advantage Manufacturing Execution System	Released
PR-0011448	Ethicon Products,	Process Specification for JDE Event Build(s)	Work Instruction (Non-PPE)	Quality System	Planning	1	Process Specification for JDE Event Build(s)	Released
PR-0011449	Ethicon Products,	Process Specifications for JDE One World Finished Goods CTR / Lean Scheduling Tool	Work Instruction (Non-PPE)	Quality System	Planning	1	Process Specifications for JDE One World Finished Goods CTR / Lean Scheduling Tool	Released
PR-0011450	Ethicon Products,	Process Specification for JDE OneWorld Raw Material Schedule / Lean Scheduling Tool	Work Instruction (Non-PPE)	Quality System	Planning	1	Process Specification for JDE OneWorld Raw Material Schedule / Lean Scheduling Tool	Released
PR-0011451	Ethicon Products,	Process Specifications for JDE OneWorld Purchased Items Schedule	Work Instruction (Non-PPE)	Quality System	Procurement	1	Process Specifications for JDE OneWorld Purchased Items Schedule	Released
PR-0011453	Ethicon Products,	Process Specifications for JDE OneWorld Suggested Quantity To Schedule	Work Instruction (Non-PPE)	Quality System	Planning	2	Process Specifications for JDE OneWorld Suggested Quantity To Schedule	Released
PR110-001	Ethicon Products,	Process Specification for JDE OneWorld Supply Planning Inquiries	Work Instruction (Non-PPE)	Quality System	Planning	1	Process Specification for JDE OneWorld Supply Planning Inquiries	Released
PR120-005	Ethicon Products,	Process Specifications for JDE OneWorld Supply Planning Reports	Work Instruction (Non-PPE)	Quality System	Planning	1	Process Specifications for JDE OneWorld Supply Planning Reports	Released
PR120-011	Ethicon Products,	Process Specifications for JDE OneWorld Rhythm and Factor Maintenance	Work Instruction (Non-PPE)	Quality System	Planning	1	Process Specifications for JDE OneWorld Rhythm and Factor Maintenance	Released
PR150-018	Ethicon Products,	Work Instructions related to Creating/Maintaining Routes, Work Centers, Standard Operations, and Shop Floor Calendar	Work Instruction (Non-PPE)	Quality System	Planning	2	Work Instructions related to Creating/Maintaining Routes, Work Centers, Standard Operations, and Shop Floor Calendar	Released
PR153-005	Ethicon Products,	PROCESS SPECIFICATION FOR CREATING REPORT FROM JDE SYSTEM, FOR TRACKING IQA QUANTITY RETURNED FROM MES SYSTEM.	Work Instruction (Non-PPE)	Quality System	Identification and Traceability	1	PROCESS SPECIFICATION FOR CREATING REPORT FROM JDE SYSTEM, FOR TRACKING IQA QUANTITY RETURNED FROM MES SYSTEM.	Released
PR157-012	Ethicon Products,	Process Specification for Thunderbird Artwork System	Work Instruction (Non-PPE)	Quality System	Packaging and Labeling	3	Process Specification for Thunderbird Artwork System	Released
PR160-001	Ethicon Products,	Process Specification for B/R Model 9300 High Purity Solvent Recycling System with Microprocessor	Work Instruction (Non-PPE)	Quality System	Calibration and Measuring Equipment	2	Process Specification for B/R Model 9300 High Purity Solvent Recycling System with Microprocessor	Released
PR161-001	Ethicon Products,	Process Specification for samples to be submitted to Preclinical Research for Testing.	Work Instruction (Non-PPE)	Quality System	Design and Development	2	Process Specification for samples to be submitted to Preclinical Research for Testing.	Released
PR161-001	Ethicon-Somerville-WW Quality System	Work Instructions for Equipment and Process Control Procedure	Procedure			24		
PR162-021	Ethicon Products,	Process Specifications for the Inspection, Maintenance, Calibration, and Use of the Corning 440 pH Meter	Work Instruction (Non-PPE)	Quality System	Calibration and Measuring Equipment	1	Process Specifications for the Inspection, Maintenance, Calibration, and Use of the Corning 440 pH Meter	Released
PR251-010	Ethicon Products,	Process Specification for JD Edwards One World Change Management	Procedure (Non-PPE)	Quality System	All Quality System Processes	5	Process Specification for JD Edwards One World Change Management	Released
PR304-008	Ethicon Products,	Work Instructions for Updating the ETHICON Records Coordinator/Department Head Contact List	Work Instruction (Non-PPE)	Quality System	Record Management	5	Work Instructions for Updating the ETHICON Records Coordinator/Department Head Contact List	Released
PR354-001	Ethicon Products,	Work Instructions - Manually Receive PO for PFG with Outside Processing	Work Instruction (Non-PPE)	Quality System	Planning	2	Work Instructions - Manually Receive PO for PFG with Outside Processing	Released
PR400-002	Ethicon Products,	Process Specification for Operating the Automatic Suture Diameter Measuring Instrument (ASDMI) in Corporate Product Characterization.	Work Instruction (Non-PPE)	Quality System	Design and Development	1	Process Specification for Operating the Automatic Suture Diameter Measuring Instrument (ASDMI) in Corporate Product Characterization.	Released
PR401-001	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Operating Procedure for Instron Mechanical Testers in Performance Evaluation R&D.	Work Instruction (Non-PPE)	Quality System	Design and Development	7	Operating Procedure for Instron Mechanical Testers in Performance Evaluation R&D.	Released
PR405-001	Ethicon Products,	Operating Procedure for the ARES Rheometer in Corporate Product Characterization.	Work Instruction (Non-PPE)	Quality System	Design and Development	1	Operating Procedure for the ARES Rheometer in Corporate Product Characterization.	Released

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PR450-003	Ethicon Products, J&J Wound Management,	Operating Procedure for Heidon Surface Analyzer 14DR in Corporate Product Characterization.	Work Instruction (Non-PPE)	Quality System	Design and Development	1	Operating Procedure for Heidon Surface Analyzer 14DR in Corporate Product Characterization.	Released
PR503-004	Ethicon Products, J&J Wound Management,	Operating Procedure for OmniSprint Optical System in Corporate Product Characterization.	Work Instruction (Non-PPE)	Quality System	Design and Development	1	Operating Procedure for OmniSprint Optical System in Corporate Product Characterization.	Released
PR504-003	Ethicon Products, J&J Wound Management,	Operating Procedure for Nikon Microscope in Corporate Product Characterization.	Work Instruction (Non-PPE)	Quality System	Design and Development	1	Operating Procedure for Nikon Microscope in Corporate Product Characterization.	Released
PR504-004	Ethicon Products, J&J Wound Management,	Operating Procedure for MTS Fatigue Tester in Corporate Product Characterization.	Work Instruction (Non-PPE)	Quality System	Design and Development	1	Operating Procedure for MTS Fatigue Tester in Corporate Product Characterization.	Released
PR504-005	Ethicon Products,	Operating Procedure for X-Ray Diffractometer in Corporate Product Characterization.	Work Instruction (Non-PPE)	Quality System	Design and Development	1	Operating Procedure for X-Ray Diffractometer in Corporate Product Characterization.	Released
PR551-005	Ethicon Products, J&J Wound Management,	Clinical Development Vendor Database Guideline	Procedure (Non-PPE)	Quality System	Customer Service	1	Clinical Development Vendor Database Guideline	Released
PR557-003	Ethicon-Somerville-Quality Systems and Compliance	COMPANY PROCEDURE FOR THE COMPILED OF A DEVICE HISTORY RECORD	Procedure			6		
PR558-006	Ethicon Products,	Process Steps for Archiving of Regulatory Affairs Vital Records-Paper & Electronic	Procedure (Non-PPE)	Quality System	Record Management	2	Process Steps for Archiving of Regulatory Affairs Vital Records-Paper & Electronic	Released
PR563-001	Ethicon Products, J&J Wound Management,	Clinical Development Risk Assessment Guideline for Non-Validated Computer Programs, Software, and Application	Procedure (Non-PPE)	Quality System	Risk Management	1	Clinical Development Risk Assessment Guideline for Non-Validated Computer Programs, Software, and Application	Released
PR563-002	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Global ETHICON Investigator Initiated Study (IIS) Review Process Guidance Document	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	Global ETHICON Investigator Initiated Study (IIS) Review Process Guidance Document	Released
PR563-003	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CLINICAL DEVELOPMENT WORK INSTRUCTIONS FOR THE CREATION AND USE OF STANDARD CRF MODULES	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
PR566-006	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Clinical Development and Medical Affairs Work Instructions for Handling Major Protocol Deviations	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	Clinical Development and Medical Affairs Work Instructions for Handling Major Protocol Deviations	Released
PR566-011	Ethicon Products, J&J Wound Management, Women's Health and Urology,	WORK INSTRUCTIONS FOR THE CREATION OF RANDOMIZATION ENVELOPES FOR CLINICAL STUDIES	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
PR566-011		Company Procedures for Decontamination of Product Complaint Samples	Procedure (Non-PPE)			18		
PR571-001	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CLINICAL DEVELOPMENT WORK INSTRUCTIONS FOR VALIDATING EDIT CHECKS WITHIN ORACLE CLINICAL	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
PR572-002	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS GUIDELINE ON RECEIPT OF CLINICAL DATA	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
PR572-002	Ethicon-Somerville-WW Quality System	STATISTICAL TECHNIQUES PROCEDURE	Procedure			9		
PR574-001	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS GUIDELINE ON DISTRIBUTING UNVALIDATED DATA LISTINGS	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
PR574-001	Ethicon-Somerville-Quality Systems and Compliance	PROCEDURE FOR PACKAGE DEVELOPMENT	Procedure			11		
PR575-003	Ethicon Products, J&J Wound Management, Women's Health and Urology,	ACCEPTANCE CRITERIA FOR ELECTRONICALLY TRANSMITTED NON-CRF CLINICAL DATA GUIDELINE	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
PR575-003	Ethicon-Somerville-WW Quality System	Company Procedure for CPAS Application Administration	Procedure			7		
PR575-003	Ethicon-Somerville-WW Quality System	Company Procedure for CPAS Application Administration	Procedure			7		
PR600-004	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS WORK INSTRUCTIONS FOR SELF-EVIDENT CORRECTIONS	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
PR600-005	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS WORK INSTRUCTIONS FOR SELF-EVIDENT CORRECTIONS	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
PR600-006	Ethicon Products, J&J Wound Management, Women's Health and Urology,	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS GUIDELINE ON REVIEW OF CLINICAL DATA	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
PR600-007	Ethicon-Somerville-WW Quality System	Work Instructions for Performing GLP QA Archiving	Procedure			3		
PR600-011	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Clinical Development Guideline for Utilizing the Laboratory Normal Range System within ORACLE Clinical	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	na	Released

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PR602-003		Franchise Procedure for Medical Device Risk Management Plan	Procedure (Non-PPE)			20 (21)		
PR602-005	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Clinical Development and Medical Affairs Work Instruction for the Creation of the Data Definitions Document	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
PR652-007	Ethicon Products,	Process Specification for the ETHICON Pilgrim Q&MIS Calibration System Setup.	Work Instruction (Non-PPE)	Quality System	Calibration and Measuring Equipment	1	Process Specification for the ETHICON Pilgrim Q&MIS Calibration System Setup.	Released
PR652-008	Ethicon Products,	Operating Procedure for Purchasing Consignment Raw materials and Reconciliation of Ethicon Owned Inventory at the Supplier using JD Edwards.	Work Instruction (Non-PPE)	Quality System	Procurement	1	Operating Procedure for Purchasing Consignment Raw materials and Reconciliation of Ethicon Owned Inventory at the Supplier using JD Edwards.	Released
PR652-009	Ethicon Products, J&J Wound Management, Women's Health and Urology,	WORK INSTRUCTIONS FOR User Maintenance Procedure for The Thunderbird Artwork Generation System	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	WORK INSTRUCTIONS FOR User Maintenance Procedure for The Thunderbird Artwork Generation System	Released
PR800-015	Ethicon Products, J&J Wound Management, Women's Health and Urology,	GRAPHICS REQUEST MANAGEMENT SYSTEM	Work Instruction (Non-PPE)	Quality System	Packaging and Labeling	5	GRAPHICS REQUEST MANAGEMENT SYSTEM	Released
PR800-018	Ethicon Products,	Process Specification for retrieving Sterility Release data for viewing post-retirement.  Note: Luis Blanco approving for San Angelo Quality	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	1	Process Specification for retrieving Sterility Release data for viewing post-retirement.  Note: Luis Blanco approving for San Angelo Quality	Released
PR800-022	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Processing of Changes in ECCS by Change Analyst	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	Processing of Changes in ECCS by Change Analyst	Released
PR800-023	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Ethicon Work Instruction for Fault Tree Analysis	Procedure (Non-PPE)	Quality System	Corrective and Preventive Actions	1	Ethicon Work Instruction for Fault Tree Analysis	Released
PR800-026	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Process Specification for Procurement Management Review	Procedure (Non-PPE)	Quality System	Management Responsibility	1	Process Specification for Procurement Management Review	Released
PR850-002	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Process Specification for Somerville Site Training Procedure	Procedure (Non-PPE)	Quality System	Training	2	Process Specification for Somerville Site Training Procedure	Released
PS-0000001	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Process Specification for Ordering and Reviewing External Standards and Directives	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	3	na	Released
PS-0000001	Ethicon-Somerville-WW Quality System	Process Specification for the ETHICON Change Control System Business Administration Process	Procedure			9		
PS-0000001	Ethicon-Somerville-WW Quality System	Process Specification for the ETHICON Change Control System Business Administration Process	Procedure			9		
PS-0000002	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Process Specification for Clinical Development Contractor Training Records at Kirkton Campus	Procedure (Non-PPE)	Quality System	Training	1	Process Specification for Clinical Development Contractor Training Records at Kirkton Campus	Released
PS-0000002	Ethicon-Somerville-WW Quality System	Process Specification for the Paper-Based Document Management Process	Procedure			5		
PS-0000002	Ethicon-Somerville-WW Quality System	Process Specification for the Paper-Based Document Management Process	Procedure			5		
PS-0000003	Ethicon Products,	ETHICON Process Specification for the Centralization of Offsite Records Storage.	Procedure (Non-PPE)	Quality System	Record Management	1	ETHICON Process Specification for the Centralization of Offsite Records Storage.	Released
PS-0000004	Ethicon Products, J&J Wound Management, Women's Health and Urology,	2nd Level Field Action Consignee List Process	Procedure (Non-PPE)	Quality System	Internal and Third Party Audits	1	2nd Level Field Action Consignee List Process	Released
PS-0000005	Ethicon Products,	ASSIGNMENT OF LOT NUMBERS AND CROSS-REFERENCE INFORMATION	Procedure (Non-PPE)	Quality System	Identification and Traceability	135 (136)	ASSIGNMENT OF LOT NUMBERS AND CROSS-REFERENCE INFORMATION	Released
PS-0000006	Ethicon Products,	ASSIGNMENT OF LOT NUMBERS FOR MONOMERS, POLYMERS, COPOLYMERS AND THEIR COMPONENTS	Procedure (Non-PPE)	Quality System	Identification and Traceability	13	ASSIGNMENT OF LOT NUMBERS FOR MONOMERS, POLYMERS, COPOLYMERS AND THEIR COMPONENTS	Released
PS-0000007	Ethicon Products,	PROCESS SPECIFICATION FOR COMPUTER ABBREVIATIONS FOR PRODUCT AND COMPONENTS	Work Instruction (Non-PPE)	Quality System	Identification and Traceability	15	PROCESS SPECIFICATION FOR COMPUTER ABBREVIATIONS FOR PRODUCT AND COMPONENTS	Released
PS-0000051	Ethicon Products, J&J Wound Management, Women's Health and Urology,	PROCEDURE FOR PACKAGE PERFORMANCE TESTING	Procedure (Non-PPE)	Quality System	Packaging and Labeling	7 (8)	PROCEDURE FOR PACKAGE PERFORMANCE TESTING	Released
PS-0000077	Ethicon Products,	WORK INSTRUCTIONS FOR PERFORMING BATCH/LOT RECORD REVIEW RELATED TO PRODUCT COMPLAINTS	Work Instruction (Non-PPE)	Quality System	Complaints, Vigilance, Recalls	9	WORK INSTRUCTIONS FOR PERFORMING BATCH/LOT RECORD REVIEW RELATED TO PRODUCT COMPLAINTS	Released
PS-0000079	Ethicon Products,	Quality Control Standards Agreement between Johnson and Johnson K.K. and ETHICON, Inc.	Procedure (Non-PPE)	Quality System	Not Specified	5	Quality Control Standards Agreement between Johnson and Johnson K.K. and ETHICON, Inc.	Released

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PS-0000080	Ethicon Products, ,	Quality Agreement between Ethicon, Inc. and Omrix Biopharmaceuticals Ltd. for Pre-Clinical Phase of the Hercules Project	Procedure (Non-PPE)	Quality System	Not Specified	4	Quality Agreement between Ethicon, Inc. and Omrix Biopharmaceuticals Ltd. for Pre-Clinical Phase of the Hercules Project	Released
PS-0000081	Ethicon Products, ,	Ethicon and Baird Industries Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon and Baird Industries Quality Agreement	Released
PS-0000083	Ethicon Products, ,	Ethicon and Mangar Industries Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	3	Ethicon and Mangar Industries Quality Agreement	Released
PS-0000085	Women's Health and Urology, ,	Ethicon and Accelgent Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	4	Ethicon and Accelgent Quality Agreement	Released
PS-0000086	Ethicon Products, ,	Ethicon & ConMed Corp Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	3	Ethicon & ConMed Corp Quality Agreement	Released
PS-0000087	Ethicon Products, ,	Ethicon & Innovative Surgical Products, Inc. (ISP) Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon & Innovative Surgical Products, Inc. (ISP) Quality Agreement	Released
PS-0000088	Ethicon Products, ,	Ethicon and J. & K. Japan Service Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon and J. & K. Japan Service Quality Agreement	Released
PS-0000089	Ethicon Products, ,	Ethicon & J-Pac, LLC Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	2	Ethicon & J-Pac, LLC Quality Agreement	Released
PS-0000090	Ethicon Products, ,	Ethicon & Sharp Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	2	Ethicon & Sharp Quality Agreement	Released
PS-0000091	Ethicon Products, ,	Ethicon & Avail- Dallas Facility Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon & Avail- Dallas Facility Quality Agreement	Released
PS-0000092	Ethicon Products, ,	Ethicon and Avail Medical Products (San Diego & Tijuana) Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1 (2)	Ethicon and Avail Medical Products (San Diego & Tijuana) Quality Agreement	Released
PS-0000094	Ethicon Products, ,	Ethicon and Ethicon Endo Surgery (EES) Customer Support Center Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon and Ethicon Endo Surgery (EES) Customer Support Center Quality Agreement	Released
PS-0000095	Ethicon Products, ,	Ethicon and Ethicon Endo Surgery (EES) Albuquerque Sterilization Facility Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1 (2)	Ethicon and Ethicon Endo Surgery (EES) Albuquerque Sterilization Facility Quality Agreement	Released
PS-0000096	Ethicon Products, ,	Ethicon and Steris Isomedix Various Sites Sterilization Facilities Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	5	Ethicon and Steris Isomedix Various Sites Sterilization Facilities Quality Agreement	Released
PS-0000097	Women's Health and Urology, ,	Ethicon, Contura and Ferrosan Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon, Contura and Ferrosan Quality Agreement	Released
PS-0000098	Women's Health and Urology, ,	Ethicon, Gyrus Medical Cardiff and Gyrus ACMI Saltillo Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	2	Ethicon, Gyrus Medical Cardiff and Gyrus ACMI Saltillo Quality Agreement	Released
PS-0000099	Women's Health and Urology, ,	Ethicon and HEI, Inc. Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon and HEI, Inc. Quality Agreement	Released
PS-0000100	Women's Health and Urology, ,	Ethicon and HEI Inc Service Center Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	2	Ethicon and HEI Inc Service Center Quality Agreement	Released
PS-0000101	Women's Health and Urology, ,	Ethicon and J & J Medical GmbH Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon and J & J Medical GmbH Quality Agreement	Released
PS-0000102	Women's Health and Urology, ,	Ethicon and J & J Medical Canada Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon and J & J Medical Canada Quality Agreement	Released
PS-0000103	Women's Health and Urology, ,	Ethicon and J & J Medical South Africa Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon and J & J Medical South Africa Quality Agreement	Released
PS-0000104	Women's Health and Urology, ,	Ethicon and J & J PROF Middle East Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon and J & J PROF Middle East Quality Agreement	Released
PS-0000105	Women's Health and Urology, ,	Ethicon and Medifix PTY LTD Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon and Medifix PTY LTD Quality Agreement	Released
PS-0000106	Women's Health and Urology, ,	Ethicon and MedTech Group Inc. Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	2	Ethicon and MedTech Group Inc. Quality Agreement	Released
PS-0000107	Women's Health and Urology, ,	Ethicon and Sterigenics Anse, France Sterilization Facility Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	2	Ethicon and Sterigenics Anse, France Sterilization Facility Quality Agreement	Released
PS-0000108	Women's Health and Urology, ,	Ethicon and Phillips Plastics Corp. Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	2	Ethicon and Phillips Plastics Corp. Quality Agreement	Released
PS-0000109	Women's Health and Urology, ,	Ethicon & GIMMI GmbH Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	2	Ethicon & GIMMI GmbH Quality Agreement	Released
PS-0000110	Ethicon Products, ,	Quality Agreement between Acclarent and Ethicon Inc.	Procedure (Non-PPE)	Quality System	Not Specified	1	Quality Agreement between Acclarent and Ethicon Inc.	Released
PS-0000111	Ethicon Products, ,	Quality Agreement between Mentor WW LLC & Ethicon Inc	Procedure (Non-PPE)	Quality System	Not Specified	3	Quality Agreement between Mentor WW LLC & Ethicon Inc	Released
PS-0000112	Ethicon Products, J&J Wound Management, ,	Quality Agreement between Ethicon and Noramco.	Procedure (Non-PPE)	Quality System	Not Specified	1	Quality Agreement between Ethicon and Noramco.	Released
PS-0000113	Women's Health and Urology, ,	Ethicon and Contura International A/S Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1	Ethicon and Contura International A/S Quality Agreement	Released
PS-0000114	Ethicon Products, ,	Keller Medical Quality Agreement for the Keller Funnel.	Procedure (Non-PPE)	Quality System	Not Specified	1	Keller Medical Quality Agreement for the Keller Funnel.	Released
PS-0000117	Ethicon Products, J&J Wound Management, Women's Health and Urology, ,	Quality Agreement for Nelson Labs	Procedure (Non-PPE)	Quality System	Not Specified	1	Quality Agreement for Nelson Labs	Released

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PS-0000117	Ethicon-Somerville-WW Quality System	Process Specification for Onsite paper and electronic record cleanout.	Procedure			16		
PS-0000117	Ethicon-Somerville-WW Quality System	Process Specification for Onsite paper and electronic record cleanout.	Procedure			16		
PS-0000131	Ethicon Products,	ATEK Medical (Costa Rica)	Procedure (Non-PPE)	Quality System	Not Specified	3 (4)	ATEK Medical (Costa Rica)	Released
PS-0000164	Ethicon Products,	STERIGENICS Quality Agreement	Procedure (Non-PPE)	Quality System	Not Specified	1 (2)	STERIGENICS Quality Agreement	Released
PS-0000167	Women's Health and Urology,	New quality agreement between Ethicon and Xion GmbH	Procedure (Non-PPE)	Quality System	Not Specified	1	New quality agreement between Ethicon and Xion GmbH	Released
PS-0000169	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Quality Agreement Between Ethicon Inc and Johnson and Johnson Medical Korea.	Procedure (Non-PPE)	Quality System	Not Specified	2	Quality Agreement Between Ethicon Inc and Johnson and Johnson Medical Korea.	Released
PS-0000193	Ethicon Products,	Quality Agreement between Ethicon and Angiotech	Procedure (Non-PPE)	Quality System	Not Specified	3	Quality Agreement between Ethicon and Angiotech	Released
PS-0000209	Women's Health and Urology,	Quality Agreement between Ethicon Inc. and Plexus.	Procedure (Non-PPE)	Quality System	Not Specified	1	Quality Agreement between Ethicon Inc. and Plexus.	Released
PS-0000210	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Quality Agreement Between Ethicon, Inc. a Johnson and Johnson Company, And Johnson and Johnson Medical (Shanghai) Ltd	Procedure (Non-PPE)	Quality System	Document Mgmt and Data Control	2	na	Released
PS-0000211	Ethicon Products,	Quality Agreement Between Ethicon,INC a Johnson and Johnson Company and Johnson and Johnson (Hong Kong) Limited.	Procedure (Non-PPE)	Quality System	Not Specified	1	Quality Agreement Between Ethicon,INC a Johnson and Johnson Company and Johnson and Johnson (Hong Kong) Limited.	Released
PS-0000212	Ethicon Products,	Quality Agreement Ethicon and JJMedical Canada - CMDR	Procedure (Non-PPE)	Quality System	Not Specified	1	Quality Agreement Ethicon and JJMedical Canada - CMDR	Released
PS-0000489		Clinical Development Risk Assessment Guideline for Non-Validated Computer Programs, Software, and Application	Procedure (Non-PPE)			1		
PS-0001047	Ethicon-Somerville-WW Quality System	Process Specification for Somerville Site Training Procedure	Procedure			2		
PS-0001047	Ethicon-Somerville-WW Quality-Post Market Surveillance	Process Specification for Somerville Site Training Procedure	Procedure			2		
PS-0001086	Ethicon-Somerville-WW Quality System	Process Specification for Ordering and Reviewing External Standards and Directives	Procedure			2		
PS-0001086	Ethicon-Somerville-WW Quality System	Process Specification for Ordering and Reviewing External Standards and Directives	Procedure			2		
PS-0001207	Ethicon-Somerville-WW Quality System	ETHICON Process Specification for the Centralization of Offsite Records Storage.	Procedure			1		
PS-0001207	Ethicon-Somerville-WW Quality System	ETHICON Process Specification for the Centralization of Offsite Records Storage.	Procedure			1		
PS254-019	Ethicon-Somerville-Quality Systems and Compliance	Process Safety Mangement Incident Investigation	Procedure			8		
PS607-002	Ethicon-Somerville-Quality Systems and Compliance	PROCEDURE FOR PACKAGE PERFORMANCE TESTING	Procedure			7		
PT-0012105	Ethicon-Somerville-Quality Systems and Compliance	Permanent Transfer of Records Located at ETHICON, Inc. Raleigh, NC for Permanent Custodial Ownership	Protocol			3		
PT-0012105	Ethicon-Somerville-WW Quality-NPI/LCM	Permanent Transfer of Records Located at ETHICON, Inc. Raleigh, NC for Permanent Custodial Ownership	Protocol			3		
QA-0000010	Ethicon Products, J&J Wound Management,	Pilgrim Audit Survey Training Materials	Work Instruction (Non-PPE)	Quality System	Training	1	Pilgrim Audit Survey Training Materials	Released
QA-0000011	Ethicon Products,	User Manual for the Corrective Preventive Action System (CPAS)	Work Instruction (Non-PPE)	Quality System	Corrective and Preventive Actions	1	User Manual for the Corrective Preventive Action System (CPAS)	Released
QA-0000012	Ethicon Products, J&J Wound Management,	User Manual for the Product Recall Application v4	Work Instruction (Non-PPE)	Quality System	Risk Management	1	User Manual for the Product Recall Application v4	Released
QA-0000013	Ethicon Products,	Print Operator User Manual for Thunderbird Artwork Generation System	Work Instruction (Non-PPE)	Quality System	Packaging and Labeling	4	Print Operator User Manual for Thunderbird Artwork Generation System	Released
QA-0000014	Ethicon Products,	Print Supervisor Manual for Thunderbird Artwork Generation System	Work Instruction (Non-PPE)	Quality System	Packaging and Labeling	1	Print Supervisor Manual for Thunderbird Artwork Generation System	Released
QA-0000015	Ethicon Products,	Product Graphics User Manual the Thunderbird Artwork Generation System	Work Instruction (Non-PPE)	Quality System	Packaging and Labeling	2	Product Graphics User Manual the Thunderbird Artwork Generation System	Released
QA-0000016	Ethicon Products,	QA Operator User Manual for Thunderbird Artwork Generation System	Work Instruction (Non-PPE)	Quality System	Packaging and Labeling	3	QA Operator User Manual for Thunderbird Artwork Generation System	Released
QA-0000017	Ethicon Products,	Viewer Manual for the Thunderbird Artwork Generation System	Work Instruction (Non-PPE)	Quality System	Packaging and Labeling	2	Viewer Manual for the Thunderbird Artwork Generation System	Released
QA-0000020	Ethicon Products,	Business Administrator Manual for the Corrective and Preventive Action System	Work Instruction (Non-PPE)	Quality System	Corrective and Preventive Actions	4	Business Administrator Manual for the Corrective and Preventive Action System	Released
QA-0000021	Ethicon Products, J&J Wound Management, Women's Health and Urology,	User Manual for System Administrator Exception Report Handling for Quid 2	Work Instruction (Non-PPE)	Quality System	Document Mgmt and Data Control	1	User Manual for System Administrator Exception Report Handling for Quid 2	Released

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QA-0000022	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Users Manual for Measurement of Alanine Dosimeters with the BRUKER BIOSPIN e-scanTM EPR (Electron Paramagnetic Resonance) Spectrometer	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	2	Users Manual for Measurement of Alanine Dosimeters with the BRUKER BIOSPIN e-scanTM EPR (Electron Paramagnetic Resonance) Spectrometer	Released
QA-0000024	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Users Manual for Calibration of the BRUKER BIOSPIN e-scanTM Alanine Dosimetry System	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	2	Users Manual for Calibration of the BRUKER BIOSPIN e-scanTM Alanine Dosimetry System	Released
QA-0000026	Ethicon Products,	Work Instruction for Ethicon ABC Classification & Strategic Flag	Work Instruction (Non-PPE)	Quality System	Procurement	4	na	Released
QA-0000028	Ethicon Products,	Segment Flag Renewal	Work Instruction (Non-PPE)	Quality System	Procurement	5	na	Released
100042078	Ethicon-Somerville-Regulatory Affairs	Qualification Protocol for Heightened Inspection of Bone Wax	Protocol			1		
100042079	Ethicon-Somerville-Regulatory Affairs	Protocol to Evaluate Foil Packaging Change of US Bone Wax Product Codes	Protocol			1		
100044026	Ethicon-Norderstedt-Regulatory Affairs and Compliance	Smvl QA IOC Inspection Protocol BV130-5 Bihler OQ	Protocol			1		
100047216	Ethicon-Somerville-Regulatory Affairs	Protocol to establish manual ECNT requirements for BV175	Protocol			1		
100060502	Ethicon-Somerville-Regulatory Affairs	Smvl QA IOC Inspection Protocol BV130-5 Bihler PQ	Protocol			1		
100065102	Ethicon-Somerville-Regulatory Affairs	Build Protocol for Bone Wax manufactured at Sharp and Inspected at Somerville RMAQ	Protocol			1		
100081072	Ethicon-Somerville-Regulatory Affairs	eDHF Transition to ADAPTIV Protocol - Mentor	Protocol			1		
100083984	Ethicon-Somerville-Regulatory Affairs	Protocol for Site to Site Reproducibility Assessment of In-Vivo Testing in Pre-Clinical Lab, Germany	Protocol			1		
100085519	Ethicon Products, J&J Wound Management, Women's Health and Urology,	OPERATING PROCEDURE FOR 510 (k) PREMARKET NOTIFICATION	Procedure (Non-PPE)	Quality System	Design and Development	4	OPERATING PROCEDURE FOR 510 (k) PREMARKET NOTIFICATION	Released
100086696	Ethicon Products, J&J Wound Management, Women's Health and Urology,	OPERATING PROCEDURE FOR PREMARKET APPROVAL APPLICATION PROCEDURE FOR MEDICAL DEVICES	Procedure (Non-PPE)	Quality System	Design and Development	3	OPERATING PROCEDURE FOR PREMARKET APPROVAL APPLICATION PROCEDURE FOR MEDICAL DEVICES	Released
DDWG-0000101	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Procedure for the Preparation of Technical Files and Design Dossiers	Procedure (Non-PPE)	Quality System	Design and Development	19 (20)	na	Released
OP608-007		OPERATING PROCEDURE FOR 510 (k) PREMARKET NOTIFICATION	Procedure (Non-PPE)			4		
OP608-011	Not Specified	Procedure for the Preparation of Technical Files and Design Dossiers	Procedure (Non-PPE)			19 (20)		
OP608-016	Complaints, Vigilance, Recalls	Procedure for A Global Regulatory Strategy	Procedure (Non-PPE)			15		
PR-0000215	Ethicon Products,	Work Instructions for Export of U.S. FDA Approved and Non Approved Medical Devices	Procedure (Non-PPE)	Quality System	Compliance	2	Work Instructions for Export of U.S. FDA Approved and Non Approved Medical Devices	Released
PR-0000222	Complaints, Vigilance, Recalls	Procedure for documentation for Japan PAL	Procedure (Non-PPE)			2		
PR-0000277	Complaints, Vigilance, Recalls	Franchise Procedure for Evaluation of Clinical Data for CE-Marking	Procedure (Non-PPE)			5		
PR-0000527	Ethicon-Norderstedt-Regulatory Affairs and Compliance	Company Procedure for Product End of Life Management	Procedure			1		
PR-0000592	Complaints, Vigilance, Recalls	Franchise Procedure for a Global Regulatory Strategy	Procedure (Non-PPE)			3		
PR-0000592		Franchise Procedure for a Global Regulatory Strategy	Procedure (Non-PPE)			3		
PR-0011357	Complaints, Vigilance, Recalls	Eskalation bei Qualitäts- und regulatorischen Problemen (SOP 1-03)	Procedure (Non-PPE)			1		
PR-0011358	Complaints, Vigilance, Recalls	Durchführung sicherheitsrelevanter korrektriver Massnahmen im Markt / FSCA (SOP 3-02)	Procedure (Non-PPE)			1		
PR-0011368		Regulatory Impact Assessment Process in the ADAPTIV System	Procedure (Non-PPE)			1		
PR555-007	Ethicon-Norderstedt-Regulatory Affairs and Compliance	Guidelines for Applying Reliability methods during Product Development	Procedure			1		
PR563-002	Ethicon-Norderstedt-Regulatory Affairs and Compliance	Company Procedure for the Control of Nonsaleable, Developmental Products and Materials Which Are Not Intended For Human or Animal Use	Procedure			9		
PR572-001	Ethicon-Norderstedt-Regulatory Affairs and Compliance	DESCRIPTIVE STATISTICS FOR ATTRIBUTE SAMPLING PLANS	Procedure			9		
PR800-002	Ethicon-Norderstedt-Regulatory Affairs and Compliance	Company Procedure for Test Method Validation	Procedure			12		
PS-0000538	Ethicon Products,	Bone Wax Regulatory Supplement R	PPE Record	Regulatory Supplement	na	2	Bone Wax Regulatory Supplement R	Released
PS-0000559	Ethicon Products,	ENDOKNOT PDSII Regulatory Supplement_AF	PPE Record	Regulatory Supplement	na	1	ENDOKNOT PDSII Regulatory Supplement_AF	Released
PS-0000559	Ethicon Products,	ENDOKNOT VICRYL Regulatory Supplement AD	PPE Record	Regulatory Supplement	na	1	ENDOKNOT VICRYL Regulatory Supplement AD	Released

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PS-0000572	Ethicon Products,	ENDOLOOP PDS II Regulatory Supplement AG	PPE Record	Regulatory Supplement	na	2	ENDOLOOP PDS II Regulatory Supplement AG	Released
PS-0000572	Ethicon Products,	ENDOLOOP VICRYL Regulatory Supplement AE	PPE Record	Regulatory Supplement	na	1	ENDOLOOP VICRYL Regulatory Supplement AE	Released
PS-0000607	Ethicon Products,	ENDOPOUCH Specimen Retrieval Bag Regulatory Supplement AI	PPE Record	Regulatory Supplement	na	1	ENDOPOUCH Specimen Retrieval Bag Regulatory Supplement AI	Released
PS-0000607	Ethicon Products,	E-PACK Regulatory Supplement J	PPE Record	Regulatory Supplement	na	3	E-PACK Regulatory Supplement J	Released
PS-0000620	Ethicon Products,	ETHIBOND Regulatory Supplement F	PPE Record	Regulatory Supplement	na	3	ETHIBOND Regulatory Supplement F	Released
PS-0000620	Ethicon Products,	ETHILON Regulatory Supplement E	PPE Record	Regulatory Supplement	na	3	ETHILON Regulatory Supplement E	Released
PS-0000652	Ethicon Products,	ETHIPACK Stainless Steel _ Non-Sterile Regulatory Supplement U	PPE Record	Regulatory Supplement	na	2	ETHIPACK Stainless Steel _ Non-Sterile Regulatory Supplement U	Released
PS-0000662	Ethicon Products,	INTERCEED_TC-7_ Absorbable Adhesion Barrier Regulatory Supplement AL	PPE Record	Regulatory Supplement	na	2	INTERCEED_TC-7_ Absorbable Adhesion Barrier Regulatory Supplement AL	Released
PS-0000668	Ethicon Products,	J-VAC Closed Wound Drainage System Regulatory Supplement AK-1 J-VAC Reservoirs	PPE Record	Regulatory Supplement	na	1	J-VAC Closed Wound Drainage System Regulatory Supplement AK-1 J-VAC Reservoirs	Released
PS-0000672	Ethicon Products,	J-VAC Closed Wound Drainage System Regulatory Supplement AK-2 J-VAC Bulb Reservoirs	PPE Record	Regulatory Supplement	na	2	J-VAC Closed Wound Drainage System Regulatory Supplement AK-2 J-VAC Bulb Reservoirs	Released
PS-0000672	Ethicon Products,	J-VAC Closed Wound Drainage System Regulatory Supplement AK-3 J-VAC Drain Adapters	PPE Record	Regulatory Supplement	na	2	J-VAC Closed Wound Drainage System Regulatory Supplement AK-3 J-VAC Drain Adapters	Released
PS-0000673	Ethicon Products,	J-VAC Closed Wound Drainage System Regulatory Supplement AK-4, Blake Silicone Drains, Round Blake Hubless Silicone Drains	PPE Record	Regulatory Supplement	na	2	J-VAC Closed Wound Drainage System Regulatory Supplement AK-4, Blake Silicone Drains, Round Blake Hubless Silicone Drains	Released
PS-0000673	Ethicon Products,	LAPRATTY Suture Clip Regulatory Supplement AC	PPE Record	Regulatory Supplement	na	1	LAPRATTY Suture Clip Regulatory Supplement AC	Released
PS-0000697	Ethicon Products,	MERSILENE Regulatory Supplement N	PPE Record	Regulatory Supplement	na	3	MERSILENE Regulatory Supplement N	Released
PS-0000712	Ethicon Products,	MERSILENE Tape Regulatory Supplement Q	PPE Record	Regulatory Supplement	na	1	MERSILENE Tape Regulatory Supplement Q	Released
PS-0000823	Ethicon Products,	MONOCRYL Regulatory Supplement H	PPE Record	Regulatory Supplement	na	3	MONOCRYL Regulatory Supplement H	Released
PS-0000899	Ethicon Products,	NUROLON Regulatory Supplement I	PPE Record	Regulatory Supplement	na	3	NUROLON Regulatory Supplement I	Released
PS-0000929	Ethicon Products,	PDS Regulatory Supplement B	PPE Record	Regulatory Supplement	na	3	PDS Regulatory Supplement B	Released
PS-0000929	Ethicon-Norderstedt-Regulatory Affairs and Compliance	Ethicon Work Instruction for Fault Tree Analysis	Procedure			1		
PS-0000954	Ethicon Products,	PROLENE Mesh Regulatory Supplement M-1, PROLENE Mesh and Soft PROLENE Mesh	PPE Record	Regulatory Supplement	na	3	PROLENE Mesh Regulatory Supplement M-1, PROLENE Mesh and Soft PROLENE Mesh	Released
PS-0001034	Ethicon Products,	PROLENE Mesh Regulatory Supplement M-2, PROLENE Hernia System	PPE Record	Regulatory Supplement	na	3	PROLENE Mesh Regulatory Supplement M-2, PROLENE Hernia System	Released
PS-0001034	Ethicon Products,	PROLENE Mesh Regulatory Supplement M-3, 3DP	PPE Record	Regulatory Supplement	na	3	PROLENE Mesh Regulatory Supplement M-3, 3DP	Released
PS-0001047	Ethicon Products,	PROLENE Regulatory Supplement C	PPE Record	Regulatory Supplement	na	3	PROLENE Regulatory Supplement C	Released
PS-0001053	Ethicon Products,	PRONOVA Regulatory Supplement G	PPE Record	Regulatory Supplement	na	2	PRONOVA Regulatory Supplement G	Released
PS-0001053	Ethicon Products,	PROXI-STRIP Regulatory Supplement S	PPE Record	Regulatory Supplement	na	2	PROXI-STRIP Regulatory Supplement S	Released
PS-0001086	Ethicon Products,	Siliconized Silk Regulatory Supplement T	PPE Record	Regulatory Supplement	na	1	Siliconized Silk Regulatory Supplement T	Released
PS-0001174	Ethicon Products,	Silk Regulatory Supplement D	PPE Record	Regulatory Supplement	na	3	Silk Regulatory Supplement D	Released
PS-0001174	Ethicon Products,	Surgical Steel _Sterile_ Regulatory Supplement K	PPE Record	Regulatory Supplement	na	2	Surgical Steel _Sterile_ Regulatory Supplement K	Released
PS-0001207	Ethicon Products,	Temporary Cardiac Pacing Wire_TcPW_ Regulatory Supplement O	PPE Record	Regulatory Supplement	na	1	Temporary Cardiac Pacing Wire_TcPW_ Regulatory Supplement O	Released
PS-0001209	Ethicon Products,	VICRYL Mesh Regulatory Supplement L	PPE Record	Regulatory Supplement	na	2	VICRYL Mesh Regulatory Supplement L	Released
PS606-001	Ethicon Products,	VICRYL Regulatory Supplement A	PPE Record	Regulatory Supplement	na	3	VICRYL Regulatory Supplement A	Released
PS606-002	Ethicon Products,	X-TRACT Tissue Morcellator Hand Piece Regulatory Supplement AA	PPE Record	Regulatory Supplement	na	1	X-TRACT Tissue Morcellator Hand Piece Regulatory Supplement AA	Released
PS606-020	Ethicon Products,	X-TRACT Laparoscopic MDU_Morcellator_Regulatory Supplement Z	PPE Record	Regulatory Supplement	na	1	X-TRACT Laparoscopic MDU_Morcellator_Regulatory Supplement Z	Released
PS607-001	Ethicon Products,	Blake Silicone Drain Japan Supplement AX (Seihin Hyojun Sho)	PPE Record	Regulatory Supplement	na	1	Blake Silicone Drain Japan Supplement AX (Seihin Hyojun Sho)	Released

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PS607-002	Ethicon Products,	Dermabond Topical Skin Adhesive Supplement AW	PPE Record	Regulatory Supplement	na	5	Dermabond Topical Skin Adhesive Supplement AW	Released
PS607-020	Ethicon Products,	BLAKE Cardio Connector Regulatory Supplement AZ	PPE Record	Regulatory Supplement	na	1	BLAKE Cardio Connector Regulatory Supplement AZ	Released
QA-0000003	Women's Health and Urology,	Regulatory Supplement for GYNEMESH_ Supplement BA	PPE Record	Regulatory Supplement	na	1	Regulatory Supplement for GYNEMESH_ Supplement BA	Released
QA-0000005	Women's Health and Urology,	Regulatory Supplement for GYNECARE Laparoscopic Morcellator Supplement AA1	PPE Record	Regulatory Supplement	na	1	Regulatory Supplement for GYNECARE Laparoscopic Morcellator Supplement AA1	Released
QA-0000008	Ethicon Products,	Regulatory Supplement for VICRYL Plus Suture, Supplement AY	PPE Record	Regulatory Supplement	na	1	Regulatory Supplement for VCRYL Plus Suture, Supplement AY	Released
100050754	Ethicon-Somerville-Research and Development-EPD Needle Technology	Extrusion PQ Protocol	Protocol			1		
100055337	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Protocol for Performance Qualification (PQ) of Internal Surgical Sealant Chemical Processes used for	Protocol			1		
100055337	Ethicon-Somerville-Research and Development-EP	Protocol for Performance Qualification (PQ) of Internal Surgical Sealant Chemical Processes used for	Protocol			1		
100056060	Ethicon-Somerville-Research and Development-EPD Needle Technology	Design Validation Protocol (Surgeons)	Protocol			1		
100056637	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Protocol for 6 mil EVERPOINT Attachment Development	Protocol			2		
100056637	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Dummy protocol for 6 mil EVERPOINT Development	Protocol			1		
100056713	Ethicon-Somerville-Research and Development-EPD Needle Technology	OQ Protocol for Oversized 8-0 PROLENE Extrusion on Extrusion Line #6	Protocol			1		
100057020	Ethicon-Somerville-Research and Development-EPD Needle Technology	Design Verification Testing Protocol	Protocol			1		
100057180	Ethicon-Somerville-Research and Development-EP	Ethylene oxide and ethylene chlorohydrin testing of PDS Plus products	Protocol			1		
100057211	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Protocol for 6 mil EVERPOINT Attachment Development	Protocol			1		
100057215	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Protocol for 6 mil EVERPOINT Attachment Development	Protocol			1		
100058776	Ethicon-Somerville-Research and Development-EPD Needle Technology	Design Verification and Design Validation Sample Build Protocol	Protocol			1		
100058888	Ethicon-Somerville-Research and Development-EPD Needle Technology	Protocol for PDS/MONOCRYL Bulk Spooling In Vivo Confirmation Study	Protocol			1		
100059417	Ethicon-Somerville-Research and Development-EP	Development Protocol for RVR Plus Sterilized in San Angelo	Protocol			1		
100059559	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	eDHF Transition to ADAPTIV Protocol	Protocol			1		
100060631	Ethicon-Somerville-Research and Development-EPD Needle Technology	Process Verification Protocol - Vicryl Plus Line Extension - Split Flow	Protocol			1		
100060633	Ethicon-Somerville-Research and Development-EP	Process Verification Protocol - Vicryl Plus Line Extension - San Angelo Codes	Protocol			1		
100061315	Ethicon-Somerville-Research and Development-JJ Wound Management	Dummy Protocol	Protocol			1		
100061933	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Injection Molding Confirmation for Omnex Housings following Material Change	Protocol			1		
100061933	Ethicon-Somerville-Research and Development-EP	Injection Molding Confirmation for Omnex Housings following Material Change	Protocol			1		
100062474	Ethicon-Somerville-Research and Development-EPD Needle Technology	Design Validation Protocol (Nurses, Labeling and Graphics)	Protocol			1		
100065866	Ethicon-Somerville-Research and Development-EP	Development Protocol for RVR Plus Sterilized in Scotland	Protocol			1		
100066657	Ethicon-Somerville-Research and Development-EP	Transportation Test Protocol for Vicryl Plus Line Extension	Protocol			1		
100067443	Ethicon-Somerville-Research and Development-EP	Design Verification Testing Protocol - STRATAFIX PDS Plus	Protocol			2		
100067443	Ethicon-Somerville-Research and Development-EP	Design Verification Testing Protocol - STRATAFIX PDS Plus	Protocol			1		
100068271	Ethicon-Somerville-Research and Development-EP	Vicryl Plus Line Extension - Build Protocol	Protocol			1		
100069791	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Magtrol M-Test CSV Appendix I Test Script	Protocol			1		
100069804	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Magtrol M-Test CSV Protocol	Protocol			1		
100070611	Ethicon-Somerville-Research and Development-Gynecare	gvy7ti	Protocol			1		
100071520	Ethicon-Somerville-Research and Development-EP	Build Protocol for Transportation Test Samples - Vicryl Plus Line Extension	Protocol			1		

100072375	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Operational Qualification Protocol for Vacuum Canning Process for Dolfin Pre-Form Material	Protocol			1		
100072375	Ethicon-Somerville-Research and Development-EP	Operational Qualification Protocol for Vacuum Canning Process for Dolfin Pre-Form Material	Protocol			1		
100072376	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Process Verification for US Mini Graphics Printing on Tyvek	Protocol			1		
100072376	Ethicon-Somerville-Research and Development-EP	Process Verification for US Mini Graphics Printing on Tyvek	Protocol			1		
100073741	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	DATA COLLECTION PROTOCOL FOR NEEDLE PENETRATION PERFORMANCE	Protocol			1		
100074778	Ethicon-Somerville-Research and Development-EP	RVR Paired Study - Triclosan Concentration Lower Limit Study	Protocol			1		
100075635	Ethicon-Somerville-Research and Development-EP	Transportation Test Protocol for Vicryl Plus Line Extension - Product in SOT	Protocol			1		
100076426	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Injection Molding Confirmation for Omnex Lever following Material Change	Protocol			1		
100076426	Ethicon-Somerville-Research and Development-EP	Injection Molding Confirmation for Omnex Lever following Material Change	Protocol			1		
100078953	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	eDHF Transition to ADAPTIV Protocol	Protocol			1		
100080268	Ethicon-Somerville-Research and Development-EP	Pilot study - RVR Plus sutures against Escherichia coli	Protocol			1		
100080694	Ethicon-Somerville-Research and Development-JJ Wound Management	Protocol for RVR ΓÇô Sample stability protocol for ECOG910 Near Infrared (NIR) standard samples stored	Protocol			1		
100083457	Ethicon-Somerville-Research and Development-EPD Needle Technology	Design Validation Protocol (Nurses, Labeling and Graphics) (TEST 2)	Protocol			1		
100083526	Design and Development	Procedure for Establishment Registration and Medical Device Listing	Procedure (Non-PPE)			1		
100083831	Ethicon-Somerville-Research and Development-Gynecare	Size 7-0 and 8-0 Development	Protocol			1		
100083890	Ethicon-Somerville-Research and Development-EPD Needle Technology	Downstream Processing of Yarns Produced in the Cornelia 56Dn Extrusion-run of High/Low IV/Acid PG910	Protocol			1		
100084424	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	BV175-7 Needlemaking Development Protocols	Protocol			1		
100086582	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Franchise Procedure for New Product Design Usability	Procedure			1		
100086901	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Protocol for BSI Design Control Corrective Action	Protocol			2		
100086901	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Protocol for BSI Design Control Corrective Action	Protocol			1		
100087476	Ethicon-Somerville-Research and Development-JJ Wound Management	RVR2012-006: The effects of particle size, thermal and vacuum drying of ECOG910 Oligomer	Protocol			1		
100087886	Ethicon-Somerville-Research and Development-Microbiology	BV175-7 Needle Blank RMQA Protocol	Protocol			1		
100088200	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	CC175-6 Needlemaking Development Protocols	Protocol			1		
100088878	Ethicon-Somerville-Research and Development-EPD Needle Technology	Development Protocol for RVR Plus in Zipper I	Protocol			1		
100089753	Ethicon-Somerville-Research and Development-Package Design	CC175-6 Needlemaking PQ Protocols	Protocol			1		
100090779	Ethicon-Somerville-Research and Development-JJ Wound Management	RVR2012-010: The Effect of Ambient Vacuum Drying of ECOG910 on Process and Product	Protocol			1		
100091072	Ethicon-Somerville-Research and Development-Package Design	Bihler Needlemaking PQ Protocol	Protocol			1		
100091093	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Bihler 6mil BV130-5 PQ Supplemental Protocol	Protocol			1		
100091423	Ethicon-Somerville-Research and Development-Package Design	CC175-6 Needle Blank RMQA Protocol	Protocol			1		
100094716	Ethicon-Somerville-Research and Development-JJ Wound Management	Protocol for RVR ΓÇô Sample stability protocol for ECOG910 Near Infrared (NIR) standard samples stored	Protocol			1		
100095739	Ethicon-Somerville-Research and Development-EP	Design Validation Protocol	Protocol			1		
MS158-001	Ethicon Products, J&J Wound Management, Women's Health and Urology,	Operating Procedure for Design Failure Modes and Effects Analysis	Procedure (Non-PPE)	Quality System	Risk Management	14	Operating Procedure for Design Failure Modes and Effects Analysis	Released
MWI-0000143	Ethicon-Somerville-Research and Development-EP	MANUFACTURING WORK INSTRUCTION FOR SEMPERFLO® PAIN MANAGEMENT SYSTEM KIT COMPONENTS LABELING	Procedure			1		
OP650-011		Operating Procedure for Design Failure Modes and Effects Analysis	Procedure (Non-PPE)			14		

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PR-0000173	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Preparation and Approval Process for Protocols, Amendments, and Administrative Changes for Clinical Trials	Procedure			8		
PR-0000174	Ethicon-Somerville-Research and Development-EP	Procedure for Preparation, Review, and Approval of Case Report Forms for Clinical Trials	Procedure			3		
PR-0000175	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Preparation, Review, and Approval of Informed Consent Documents for Clinical Trials	Procedure			1		
PR-0000176	Ethicon-Somerville-Research and Development-EP	Procedure for the Site Evaluation Visit for Clinical Trials	Procedure			6		
PR-0000177	Ethicon-Somerville-Research and Development-EP	Procedure for the Site Initiation Visit for Clinical Trials	Procedure			7		
PR-0000178	Ethicon-Somerville-Research and Development-EP	Procedure for the Site Monitoring Visit for Clinical Trials	Procedure			7		
PR-0000179	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for the Site Close Out for Clinical Trials	Procedure			6		
PR-0000183	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Preparing Clinical Study Reports for Clinical Trials	Procedure			3		
PR-0000190	Ethicon-Somerville-Research and Development-EP	Procedure for Oracle Clinical System Security and Disaster Recovery for Clinical Trials	Procedure			4		
PR-0000191	Ethicon-Somerville-Research and Development-EP	Clinical Development and Medical Affairs Procedure for Creation and Maintenance of the Global Library for Clinical Trials	Procedure			2		
PR-0000192	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Statistical Input into Clinical Investigation Plans / Protocols for Clinical Trials	Procedure			1		
PR-0000193	Ethicon-Somerville-Research and Development-EP	Procedure for the Creation of an Annotated Case Report Form for Clinical Trials	Procedure			4		
PR-0000194	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Randomization and Blinding for Clinical Trials	Procedure			2		
PR-0000195	Ethicon-Somerville-Research and Development-EP	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS PROCEDURE FOR A DATA MANAGEMENT PLAN FOR CLINICAL TRIALS	Procedure			4		
PR-0000196	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS PROCEDURE FOR DATA ENTRY FOR CLINICAL TRIALS IN AN ORACLE CLINICAL DATABASE	Procedure			3		
PR-0000197	Ethicon-Somerville-Research and Development-EP	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS PROCEDURE FOR THE DATABASE QUALITY CONTROL PROCESS FOR CLINICAL TRIALS	Procedure			3		
PR-0000198	Ethicon-Somerville-Research and Development-EP	Procedure for the Statistical Analysis Plan for Clinical Trials	Procedure			2		
PR-0000199	Ethicon-Somerville-Research and Development-EP	Procedure for Locking and Unlocking of a Database for Clinical Trials	Procedure			4		
PR-0000200	Ethicon-Somerville-Research and Development-EP	Procedure for Data Extraction from the Oracle Clinical Database Used for Clinical Trials	Procedure			4		
PR-0000201	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Reporting Statistical Results for Clinical Trials	Procedure			1		
PR-0000202	Ethicon-Somerville-Research and Development-EP	Clinical Development and Medical Affairs Procedure for Creation and Testing of a Database for Clinical Trials	Procedure			3		
PR-0000217	Ethicon Products, J&J Wound Management, ,	Work Instructions for the eDHF Users Manual	Work Instruction (Non-PPE)	Quality System	Design and Development	4	Work Instructions for the eDHF Users Manual	Released
PR-0000218	Ethicon Products, J&J Wound Management, ,	Work Instructions for the Electronic Design History File Business Administrators User Manual	Work Instruction (Non-PPE)	Quality System	Design and Development	5	Work Instructions for the Electronic Design History File Business Administrators User Manual	Released
PR-0000220	Ethicon Products, J&J Wound Management, ,	PR800-015 Work-Instructions for eDHF System Administrators	Work Instruction (Non-PPE)	Quality System	Design and Development	2	PR800-015 Work-Instructions for eDHF System Administrators	Released
PR-0000250	Ethicon Products, J&J Wound Management, ,	WORK INSTRUCTIONS FOR eDHF BUSINESS ADMINISTRATORS PROCEDURES	Work Instruction (Non-PPE)	Quality System	Design and Development	4	WORK INSTRUCTIONS FOR eDHF BUSINESS ADMINISTRATORS PROCEDURES	Released
PR-0000252	Ethicon-Somerville-Research and Development-EP	Procedure for Data Coding of Adverse Events, concomitant medications & Medical Histories for Clinical Trials.	Procedure			3		
PR-0000257	Ethicon-Somerville-Research and Development-EP	Procedure for creating, verifying, & monitoring accuracy of reimbursement information provided to customers and other external stakeholders by Health, Economics, & Reimbursement.	Procedure			1		
PR-0000258	Ethicon-Somerville-Research and Development-EP	Procedure for removing and correcting reimbursement information provided to customers and other external stakeholders by Health, Economics, & Reimbursement.	Procedure			1		
PR-0000271	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Company Procedure: Glossary of Clinical Definitions	Procedure			3		

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PR-0000299	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for CMDA (US) Records Management Using Global Records & Electronic Archive Tracking System (GREATS)	Procedure			OBS		
PR-0000299	Ethicon-Somerville-Research and Development-EP	Procedure for CMDA (US) Records Management Using Global Records & Electronic Archive Tracking System (GREATS)	Procedure			1		
PR-0000565	Ethicon-Somerville-Research and Development-EPD Needle Technology	Procedure for Stability Study Setup, Sample Retrieval, Handling, Testing, and Data Management of Stability Studies QA-1-043	Procedure			1		
PR-0000608	Ethicon-Somerville-Research and Development-EPD Needle Technology	ETHICON COMPANY PROCEDURE FOR INTERPRETATION OF NEW PRODUCT DEVELOPMENT DRAWINGS	Procedure			1		
PR-0000612	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Shipping Procedure for the Transportation of OMNEX Formulation to Subcontractors (San Lorenzo) PM-6-1737	Procedure			1		
PR-0000612	Ethicon-Somerville-Research and Development-EP	Shipping Procedure for the Transportation of OMNEX Formulation to Subcontractors (San Lorenzo) PM-6-1737	Procedure			1		
PR800-012	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Company Procedure For Design Changes to Existing Products	Procedure			19		
PS-0000005	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Process Specification for Creation and Revision of Needle Specifications, Needle Blanks and Needle Templates	Procedure			5		
PS-0000490	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	US Records Management Guideline for Clinical Development and Medical Affairs	Procedure			2		
PS-0000490	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	US Records Management Guideline for Clinical Development and Medical Affairs	Procedure			OBS		
PS-0000515	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Clinical Development and Medical Affairs Work Instructions for Handling Major Protocol Deviations	Procedure			1		
PS-0000538	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Clinical Development and Medical Affairs Guideline on Review of Clinical Data	Procedure			1		
PS-0000607	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Clinical Development and Medical Affairs Guideline for Utilizing the Laboratory Normal Range System within ORACLE Clinical	Procedure			1		
PS-0000987	Ethicon-Somerville-Research and Development-EP	PROCESS SPECIFICATION FOR EDUCATIONAL GRANTS	Procedure			1		
PS-0001021	Ethicon-Somerville-Research and Development-EP	Initial SOP for RMIR's (Response to Medical Information Requests)	Procedure			1		
PS-0001023	Ethicon-Somerville-Research and Development-EP	Initial SOP for SMR's (Standard Medical Responses)	Procedure			1		
QA-0000029	Ethicon-Somerville-Research and Development-EP	Pronova Design Requirements Matrix	Product Development Requirements	Design Requirements Matrix		1	DRM created for Pronova suture.	Released
QA-0000030	Ethicon-Somerville-Research and Development-EP	Design Requirements Matrix Prolene with Silicone Beads and Aluminum Collars	Product Development Requirements	Design Requirements Matrix		1	New Design Requirements Matrix Prolene with Silicone Beads and Aluminum Collars	Released
QA-0000031	Ethicon-Somerville-Research and Development-EP	Design Requirements Matrix for Prolene with Ethilock Clips	Product Development Requirements	Design Requirements Matrix		1	New Design Requirements Matrix for Prolene with Ethilock Clips	Released
QA-0000032	Ethicon-Somerville-Research and Development-EP	Design Requirements Matrix for Ethiloop	Product Development Requirements	Design Requirements Matrix		1	New Design Requirements Matrix for Ethiloop	Released
QA-0000033	Ethicon-Somerville-Research and Development-EP	ETHILON BLUE DRM	Product Development Requirements	Design Requirements Matrix		1	DRM included under the scope of a design change to bring FG721-001 (US) and SP-0007 (FR) into alignment.	Released
QA-0000034	Ethicon-Somerville-Research and Development-EP	Assembly Drawings for SemperFlo Pain Management System Microcatheter - Curved and Straight	Drawing	Device		8	Assembly Drawings for SemperFlo Pain Management System Microcatheter - Curved and Straight	Released
QA-0000035	Ethicon-Somerville-Research and Development-EP	Design Requirements Matrix for PROCEED® Surgical Mesh.	Product Development Requirements	Design Requirements Matrix		12	Design Requirements Matrix for PROCEED® Surgical Mesh.	Released
QA-0000036	Ethicon-Somerville-Research and Development-EP	DRM for Gynemesh XL	Product Development Requirements	Design Requirements Matrix		5	DRM for Gynemesh XL	Released
QA-0000038	Ethicon-Somerville-Research and Development-EP	ETHICON SECURESTRAP DESIGN REQUIREMENTS MATRIX	Product Development Requirements	Design Requirements Matrix		5	ETHICON SECURESTRAP DESIGN REQUIREMENTS MATRIX	Released
QA-0000039	Ethicon-Somerville-Research and Development-EP	Design Requirements Matrix for the DERMABOND ADVANCED Topical Skin Adhesive Product	Product Development Requirements	Design Requirements Matrix		4	Design Requirements Matrix for the DERMABOND ADVANCED Topical Skin Adhesive Product	Released
QA-0000052	Ethicon-Somerville-Research and Development-EP	Release Specification for DERMABOND ProTape_QC-5-131 QC-5-135	Specification	Finished Goods Specification	Wound Closure	6	Release Specification for DERMABOND ProTape_QC-5-131 QC-5-135	Released
QA-0000059	Ethicon-Somerville-Research and Development-EP	Material Specification for Toshiba Tungsten-Rhenium Wire (H36-ES)	Specification	Material Specification	Raw Material	7	Material Specification for Toshiba Tungsten-Rhenium Wire (H36-ES)	Released
QA-0000063	Ethicon-Somerville-Research and Development-EP	Material Specification for DERMABOND ADVANCED Formulation (OC017)	Specification	Material Specification	Component	3	Material Specification for DERMABOND ADVANCED Formulation (OC017)	Released
QA-0000064	Ethicon-Somerville-Research and Development-EP	Material Specification for Age Hardenable Stainless Steel for Channel Needles, Type 455	Specification	Material Specification	Raw Material	34	Material Specification for Age Hardenable Stainless Steel for Channel Needles, Type 455	Released
QA-0000066	Ethicon-Somerville-Research and Development-EP	Material Specification for ETHALLOY-II, ETHALLOY-II-FS and ETHALLOY-II-PS Wire	Specification	Material Specification	Raw Material	26	Material Specification for ETHALLOY-II, ETHALLOY-II-FS and ETHALLOY-II-PS Wire	Released
QA-0000067	Ethicon-Somerville-Research and Development-EP	Material Specification for Stainless Steel Needle Wire for Channel and Drilled Needles Type 420 (ETHICON*)	Specification	Material Specification	Raw Material	15	Material Specification for Stainless Steel Needle Wire for Channel and Drilled Needles Type 420 (ETHICON*)	Released

QA-0000068	Ethicon-Somerville-Research and Development-EP	BV130-5, 6 mil, Needle Blank	Drawing	Needle		A	BV130-5, 6 mil, Needle Blank	Released
QA-0000073	Ethicon-Somerville-Research and Development-EP	OPERATING PROCEDURE FOR THE SET UP AND PREVENTIVE MAINTENANCE OF TINIUS OLSEN (T/O) STIFFNESS TESTERS	PPE Work Instruction	Equipment Instruction	Equipment Instruction	1	OPERATING PROCEDURE FOR THE SET UP AND PREVENTIVE MAINTENANCE OF TINIUS OLSEN (T/O) STIFFNESS TESTERS	Released
QA-0000074	Ethicon-Somerville-Research and Development-EP	Statement of Requirements for Ethicon Bend Tester (EBT)	Specification	Software Specification	Automated Process	1	Statement of Requirements for Ethicon Bend Tester (EBT)	Released
QA-0000078	Ethicon-Somerville-Research and Development-WW	FRANCHISE PROCEDURE FOR DESIGN CHANGES TO EXISTING PRODUCTS	Procedure (Non-PPE)	Quality System	Design and Development	3	FRANCHISE PROCEDURE FOR DESIGN CHANGES TO EXISTING PRODUCTS	Released
QA-0000082	Ethicon-Somerville-Research and Development-WW	FRANCHISE POLICY FOR ETHICON'S DESIGN CONTROL OF NEW PRODUCT DEVELOPMENT	Policy	Quality System	Design and Development	1	FRANCHISE POLICY FOR ETHICON'S DESIGN CONTROL OF NEW PRODUCT DEVELOPMENT	Released
QA-0000084	Ethicon-Somerville-Research and Development-WW	Franchise Procedure for Design Control of Non-Electromechanical New Product Development	Procedure (Non-PPE)	Quality System	Design and Development	8 (9)	Franchise Procedure for Design Control of Non-Electromechanical New Product Development	Released
QA-0000085	Ethicon-Somerville-Research and Development-WW	Franchise Procedure for Design Control of New Electromechanical Product Development	Procedure (Non-PPE)	Quality System	Design and Development	4 (5)	Franchise Procedure for Design Control of New Electromechanical Product Development	Released
QA-0000087	Ethicon-Somerville-Research and Development-WW	Franchise Electromechanical Traceability Process Specification	Procedure (Non-PPE)	Quality System	Identification and Traceability	1	Franchise Electromechanical Traceability Process Specification	Released
RMR-0000010	Ethicon-Somerville-Research and Development-WW	Franchise Procedure for Controlling Substances of Concern	Procedure (Non-PPE)	Environmental Health and Safety	Environmental Health and Safety	2	Franchise Procedure for Controlling Substances of Concern	Released
RMR-0000011	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT SITE BUDGETS AND CONTRACTS	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000014	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	VALIDATING EDIT CHECKS USING ELECTRONIC DATA CAPTURE	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000015	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	USER ACCEPTANCE TESTING (UAT) USING ELECTRONIC DATA CAPTURE (EDC)	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000017	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	STUDY HOLD, INTERIM ANALYSIS AND STUDY CLOSURE USING ELECTRONIC DATA CAPTURE (EDC)	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000019	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	SITE READINESS WHEN USING ELECTRONIC DATA CAPTURE (EDC)	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000020	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	REPORTING WITHIN ELECTRONIC DATA CAPTURE (EDC) STUDIES	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000021	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	GUIDELINE FOR UTILIZING THE LAB ADMINISTRATION MODULE IN MEDIDATA RAVE	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000023	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CHANGE CONTROL PROCESSES FOR ELECTRONIC DATA CAPTURE (EDC)	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000025	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CREATION AND APPROVAL OF AN ELECTRONIC CRF FOR USE IN ELECTRONIC DATA CAPTURE	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000028	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR MEDIDATA RAVE SYSTEM SECURITY AND DISASTER RECOVERY	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000029	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	ESTABLISHMENT AND OPERATION OF DATA MONITORING COMMITTEES OR DATA SAFETY MONITORING BOARD	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000039	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	ROUTINE ADVERSE EVENT REVIEW FOR POTENTIAL SAFETY SIGNALS/TRENDS ON INVESTIGATIONAL CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000040	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR REQUESTS TO RETRIEVE BOXES FROM EXTERNAL ARCHIVE (KIRKTON CAMPUS)	Procedure (Non-PPE)	Quality System	All Quality System Processes	1	na	Released
RMR-0000041	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Medical Affairs Policy for Transferring Electronic Data	Policy	Health Care Compliance	Health Care Compliance	1	Medical Affairs Policy for Transferring Electronic Data	Released
RMR-0000042	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	POLICY ON PROVIDING COMPUTER HARDWARE AND SOFTWARE FOR CLINICAL DEVELOPMENT RESEARCH PROJECTS	Policy	Health Care Compliance	Health Care Compliance	1	POLICY ON PROVIDING COMPUTER HARDWARE AND SOFTWARE FOR CLINICAL DEVELOPMENT RESEARCH PROJECTS	Released
RMR-0000043	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Preparation, Approval, Maintenance, and Control of Procedures for Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	4	Procedure for Preparation, Approval, Maintenance, and Control of Procedures for Clinical Trials	Released
RMR-0000044	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Preparation and Approval Process for Protocols, Amendments, and Administrative Changes for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	9	Procedure for Preparation and Approval Process for Protocols, Amendments, and Administrative Changes for Clinical Trials	Released
RMR-0000047	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR PREPARATION, REVIEW, AND APPROVAL OF CASE REPORT FORMS FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	na	Released
RMR-0000049	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR PREPARATION, REVIEW, AND APPROVAL OF INFORMED CONSENT DOCUMENTS FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RMR-0000050	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR THE SITE EVALUATION VISIT FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	7	Procedure for the Site Evaluation Visit for Clinical Trials	Released
RMR-0000051	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR THE SITE INITIATION VISIT FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	8	Procedure for the Site Initiation Visit for Clinical Trials	Released
RMR-0000052	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR THE SITE MONITORING VISIT FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	8	Procedure for the Site Monitoring Visit for Clinical Trials	Released

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RMR-0000053	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR THE SITE CLOSE OUT FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	7	Procedure for the Site Close Out for Clinical Trials	Released
RMR-0000054	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Preparation, Review and Approval of the Investigator's Brochure for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	3	na	Released
RMR-0000056	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Maintaining a Trial Master File for Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	6 (7)	Procedure for Maintaining a Trial Master File for Clinical Trials	Released
RMR-0000057	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Maintaining an Investigator Trial File for Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	2 (3)	Procedure for Maintaining an Investigator Trial File for Clinical Trials	Released
RMR-0000058	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR PREPARING CLINICAL STUDY REPORTS FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	na	Released
RMR-0000059	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for the Use of a Contract Research Organization for Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	3	Procedure for the Use of a Contract Research Organization for Clinical Trials	Released
RMR-0000060	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS PROCEDURE FOR SUPPLY AND ACCOUNTABILITY OF STUDY ARTICLES FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	Design and Development	2	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS PROCEDURE FOR SUPPLY AND ACCOUNTABILITY OF STUDY ARTICLES FOR CLINICAL TRIALS	Released
RMR-0000062	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Suspicion of Misrepresentation and Misconduct for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	3	na	Released
RMR-0000063	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Adverse Event Collection and Reporting for a Pharmaceutical Clinical Trial	Procedure (Non-PPE)	Quality System	Design and Development	2	Procedure for Adverse Event Collection and Reporting for a Pharmaceutical Clinical Trial	Released
RMR-0000064	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Adverse Event Collection and Reporting for U.S. Medical Device Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	2	Procedure for Adverse Event Collection and Reporting for U.S. Medical Device Clinical Trials	Released
RMR-0000065	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Adverse Event Collection and Reporting for EU Medical Device Clinical Trials	Procedure (Non-PPE)	Not Specified	Not Specified	2	Procedure for Adverse Event Collection and Reporting for EU Medical Device Clinical Trials	Released
RMR-0000066	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Oracle Clinical System Security and Disaster Recovery for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	5	Procedure for Oracle Clinical System Security and Disaster Recovery for Clinical Trials	Released
RMR-0000067	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Clinical Development Procedure for Creation and Maintenance of the Global Library for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	3	Clinical Development Procedure for Creation and Maintenance of the Global Library for Clinical Trials	Released
RMR-0000069	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR STATISTICAL INPUT INTO CLINICAL INVESTIGATION PLANS/PROTOCOLS FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RMR-0000070	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for the Creation of an Annotated Case Report Form for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	5	Procedure for the Creation of an Annotated Case Report Form for Clinical Trials	Released
RMR-0000071	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Randomization and Blinding for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	3	Procedure for Randomization and Blinding for Clinical Trials	Released
RMR-0000072	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS PROCEDURE FOR A DATA MANAGEMENT PLAN FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	5	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS PROCEDURE FOR A DATA MANAGEMENT PLAN FOR CLINICAL TRIALS	Released
RMR-0000073	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT PROCEDURE FOR DATA ENTRY IN A CLINICAL DATA MANAGEMENT SYSTEM (CDMS)	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	CLINICAL DEVELOPMENT PROCEDURE FOR DATA ENTRY IN A CLINICAL DATA MANAGEMENT SYSTEM (CDMS)	Released
RMR-0000076	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Clinical Development Procedure for the Database Quality Control Process for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	CLINICAL DEVELOPMENT PROCEDURE FOR THE DATABASE QUALITY CONTROL PROCESS FOR CLINICAL TRIALS	Released
RMR-0000077	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR THE STATISTICAL ANALYSIS PLAN FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	3	na	Released
RMR-0000078	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR LOCKING AND UNLOCKING OF A DATABASE FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	5	Procedure for Locking and Unlocking of a Database for Clinical Trials	Released
RMR-0000081	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR DATA EXTRACTION FROM THE CLINICAL TRIAL DATABASE	Procedure (Non-PPE)	Quality System	All Quality System Processes	5	Procedure for Data Extraction from the Clinical Trial Database	Released
RMR-0000082	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR REPORTING STATISTICAL RESULTS FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RMR-0000083	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Clinical Development and Medical Affairs Procedure for Creation and Testing of a Database for Clinical Trials	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	Clinical Development and Medical Affairs Procedure for Creation and Testing of a Database for Clinical Trials	Released
RMR-0000085	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR INTERIM AND FOLLOW-UP ANALYSES FOR CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RMR-0000087	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Procedure for Registration, Assessment and Disclosure of Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	2	Procedure for Registration, Assessment and Disclosure of Clinical Trials	Released
RMR-0000104	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCEDURE FOR MEDICAL DATA CODING OF TERMS WITHIN A CLINICAL TRIAL TO A STANDARDIZED DICTIONARY	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	na	Released
RMR-0000105	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	COMPANY PROCEDURE: GLOSSARY OF CLINICAL DEFINITIONS	Procedure (Non-PPE)	Quality System	All Quality System Processes	4	na	Released
RS-0000003	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Clinical Development Vendor Database Guideline	Procedure (Non-PPE)	Quality System	Customer Service	1	Clinical Development Vendor Database Guideline	Released
RS-0000004	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Clinical Development and Medical Affairs Product Complaint and Adverse Event (AE) Reporting Process for Post-Approval Medical Device Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	4	Clinical Development and Medical Affairs Product Complaint and Adverse Event (AE) Reporting Process for Post-Approval Medical Device Clinical Trials	Released
RS-0000005	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Clinical Development Risk Assessment Guideline for Non-Validated Computer Programs, Software, and Application	Procedure (Non-PPE)	Quality System	Risk Management	1	Clinical Development Risk Assessment Guideline for Non-Validated Computer Programs, Software, and Application	Released

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RS-0000006	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Global ETHICON Investigator Initiated Study (IIS) Review Process Guidance Document	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	Global ETHICON Investigator Initiated Study (IIS) Review Process Guidance Document	Released
RS-0000007	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT WORK INSTRUCTIONS FOR THE CREATION AND USE OF STANDARD CRF MODULES	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RS-0000008	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Clinical Development and Medical Affairs Work Instructions for Handling Major Protocol Deviations	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	Clinical Development and Medical Affairs Work Instructions for Handling Major Protocol Deviations	Released
RS-0000009	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	WORK INSTRUCTIONS FOR THE CREATION OF RANDOMIZATION ENVELOPES FOR CLINICAL STUDIES	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RS-0000010	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT WORK INSTRUCTIONS FOR VALIDATING EDIT CHECKS WITHIN ORACLE CLINICAL	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RS-0000011	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS WORK INSTRUCTIONS FOR SAS PROGRAM TESTING	Work Instruction (Non-PPE)	Quality System	Validation	3	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS WORK INSTRUCTIONS FOR SAS PROGRAM TESTING	Released
RS-0000012	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS GUIDELINE ON RECEIPT OF CLINICAL DATA	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RS-0000014	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS GUIDELINE ON DISTRIBUTING UNVALIDATED DATA LISTINGS	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RS-0000015	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	ACCEPTANCE CRITERIA FOR ELECTRONICALLY TRANSMITTED NON-CRF CLINICAL DATA GUIDELINE	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RS-0000016	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS GUIDELINE ON STUDY ASSUMPTIONS	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RS-0000017	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS WORK INSTRUCTIONS FOR SELF-EVIDENT CORRECTIONS	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RS-0000018	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS GUIDELINE ON REVIEW OF CLINICAL DATA	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RS-0000019	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Process Specification for Clinical Development Employee Training Records - Kirkton Campus	Work Instruction (Non-PPE)	Quality System	Design and Development	2	Process Specification for Clinical Development Employee Training Records - Kirkton Campus	Released
RS-0000020	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCESS SPECIFICATION FOR REVIEW OF DISCLOSABLE FINANCIAL INTERESTS OF INVESTIGATORS IN US CLINICAL TRIALS	Procedure (Non-PPE)	Quality System	Design and Development	1	PROCESS SPECIFICATION FOR REVIEW OF DISCLOSABLE FINANCIAL INTERESTS OF INVESTIGATORS IN US CLINICAL TRIALS	Released
RS-0000021	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Clinical Development Guideline for Utilizing the Laboratory Normal Range System within ORACLE Clinical	Procedure (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RS-0000022	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Clinical Development and Medical Affairs Work Instruction for the Creation of the Data Definitions Document	Work Instruction (Non-PPE)	Quality System	All Quality System Processes	2	na	Released
RS-0000024	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCESS SPECIFICATION FOR MAINTAINING A TRIAL MASTER FILE FOR CLINICAL TRIALS IN EU	Procedure (Non-PPE)	Quality System	Design and Development	1 (2)	PROCESS SPECIFICATION FOR MAINTAINING A TRIAL MASTER FILE FOR CLINICAL TRIALS IN EU	Released
RS-0000025	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	PROCESS SPECIFICATION FOR MAINTAINING A TRIAL MASTER FILE FOR CLINICAL TRIALS In US	Procedure (Non-PPE)	Quality System	Design and Development	2 (3)	PROCESS SPECIFICATION FOR MAINTAINING A TRIAL MASTER FILE FOR CLINICAL TRIALS In US	Released
RS-0000026	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Process Specification For The Translation Of Clinical Study Documentation	Procedure (Non-PPE)	Quality System	Design and Development	1	Process Specification For The Translation Of Clinical Study Documentation	Released
RS-0000027	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Independent Ethics Committee / Institutional Review Board Selection and Review for Clinical Trials	Procedure (Non-PPE)	Quality System	Design and Development	1	Independent Ethics Committee / Institutional Review Board Selection and Review for Clinical Trials	Released
RS-0000028	Ethicon-Somerville-Research and Development-Clinical Development and Medical Affairs	Process Specification for Clinical Development Contractor Training Records at Kirkton Campus	Procedure (Non-PPE)	Quality System	Training	1	Process Specification for Clinical Development Contractor Training Records at Kirkton Campus	Released
RS-0000029	Ethicon-Somerville-Research and Development-EPD Needle Technology	EVERPOINT Design Requirements Matrix	Product Development Requirements	Design Requirements Matrix		12	EVERPOINT Design Requirements Matrix	Released
RS-0000030	Ethicon-Somerville-Research and Development-EPD Needle Technology	Stainless Steel Drilled Needles from Ethicon Norderstedt	Specification	Material Specification	Component	13	Stainless Steel Drilled Needles from Ethicon Norderstedt	Released
RS-0000031	Ethicon-Somerville-Research and Development-EPD Needle Technology	BV130-5, 6.5mm, 6-mil, H=0.0027",BV130-5	Drawing	Needle		B	6.5mm	6-mil
RS-0000032	Ethicon-Somerville-Research and Development-EPD Needle Technology	Radius 12 mil, R .217	Drawing	Needle		A	Radius 12 mil, R .217	Released
RS-0000033	Ethicon-Somerville-Research and Development-EPD Needle Technology	OPERATING PROCEDURE FOR PENETRATION PERFORMANCE TESTING OF SURGICAL NEEDLES (ECNT TESTING)	PPE Work Instruction	Inspection Instruction	Needle Production	75	OPERATING PROCEDURE FOR PENETRATION PERFORMANCE TESTING OF SURGICAL NEEDLES (ECNT, ETHICON CURVED NEEDLE TESTER, TESTING)	Released
RS-0000034	Ethicon-Somerville-Research and Development-EPD Needle Technology	Franchise Procedure for the Global Needle Quality Standards Committee (GNQSC)	Procedure (Non-PPE)	Quality System	Production	4	na	Released
RS-0000036	Ethicon-Somerville-Research and Development-EPD Needle Technology	Needle Strength and Ductility Requirements	PPE Work Instruction	Inspection Instruction	Needle Production	71	Needle Strength and Ductility Requirements	Released
RS-0000037	Ethicon-Somerville-Research and Development-EPD Needle Technology	TEST METHOD FOR ETHICON CURVED NEEDLE TESTER	Test Method	Physical		52	TEST METHOD FOR ETHICON CURVED NEEDLE TESTER	Released
RS-0000038	Ethicon-Somerville-Research and Development-Microbiology	Operating Procedure for Autoclave.	Work Instruction (Non-PPE)	Quality System	Sterilization and Microbiology	5	Operating Procedure for Autoclave.	Released
RS-0000039	Ethicon-Somerville-Research and Development-Microbiology	Work Instructions and Microbiological Test Requirements for the Dosimetric Auditing Program	Procedure (Non-PPE)	Quality System	Sterilization and Microbiology	75	Work Instructions and Microbiological Test Requirements for the Dosimetric Auditing Program	Released

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RS-0000040	Ethicon-Somerville-Research and Development-Microbiology	Franchise Procedure for External Manufacturers Producing Product Labeled STERILE**	PPE Work Instruction	Manufacturing Instruction	Sterilization and Microbiology	7 (8)	na	Released
RS-0000042	Ethicon-Somerville-Research and Development-Package Design	Steel, Nylon, Silk Folder Drawing (RMC F0516).	Drawing	Packaging		A	Drawing for Steel, Nylon, Silk Folder RMC F0516	Released
RS-0000044	Ethicon-Somerville-Research and Development-Package Design	Stratafix PDS + 12 count deep draw tray	Drawing	Packaging		B	Tray for Stratafix PDS Plus	Released
RS-0000046	Ethicon-Somerville-Research and Development-Package Design	Stratafix PDS + sleeve	Drawing	Packaging		A	Sleeve for Stratafix PDS + tray	Released
RS-0000047	Ethicon-Somerville-Research and Development-Package Design	Guardian Suture Tray Paper Lid	Drawing	Packaging		A	Paper Lid for Guardian Suture Tray	Released
RS-0000048	Ethicon-Somerville-Research and Development-Package Design	Guardian Tray	Drawing	Packaging		A	Plastic Tray for Barbed Suture	Released
RS-0000049	Ethicon-Somerville-Research and Development-Package Design	Horizontal 12 count Deep Draw Suture Tray	Specification	Material Specification	Packaging	1 (2)	Horizontal Tray to hold 12 count deep draw foil	Released
TM-0000177	Ethicon-Somerville-Research and Development-Package Design	Horizontal 12 Count Deep Draw Sleeve	Specification	Material Specification	Packaging	1	Sleeve for horizontal 12 count Deep Draw Tray	Released
TM403-010	Ethicon-Somerville-Research and Development-Package Design	Peelable Foil Tyvek Header Pouches-Printed	Specification	Material Specification	Packaging	5	Peelable Foil Tyvek Header Pouches-Printed (See Supporting Documentation SD-0020825 in ECCS}	Released
TM406-080	Ethicon-Somerville-Research and Development-Package Design	Material Specification for Paperboard Folding Cartons, Trays and Sleeves	Specification	Material Specification	Packaging	38	Material Specification for Paperboard Folding Cartons, Trays and Sleeves	Released
TRM-0000022	Ethicon-Somerville-Research and Development-Package Design	Drawing Folded Boxes 135 X 60 X 12mm	Drawing	Packaging		B	Drawing Folded Boxes 135 X 60 X 12mm	Released
UM-0000005	Ethicon-Somerville-Research and Development-Package Design	Drawing Folded Boxes 140X90X12 mm (PKDWG-0000304).	Drawing	Packaging		B	Drawing Folded Boxes 140X90X12 mm (PKDWG-0000304).	Released
UM-0000048	Ethicon-Somerville-Research and Development-Package Design	Harmonized Test Method for Seal Strength Measurement of Flexible Packaging Materials	Test Method	Packaging		6	Harmonized Test Method for Seal Strength Measurement of Flexible Packaging Materials	Released
UM-0000052	Ethicon-Somerville-Research and Development-Package Design	VISUAL INSPECTION OF RAW, IN-PROCESS AND FINISHED GOODS MATERIALS_English	Test Method	Physical		27 (28)	VISUAL INSPECTION OF RAW, IN-PROCESS AND FINISHED GOODS MATERIALS_English	Released
UM-0000053	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	OPERATING PROCEDURE FOR QUARTERLY ETHYLENE OXIDE BIOBURDEN AUDIT PROGRAM	Procedure (Non-PPE)	Quality System	Sterilization and Microbiology	68 (69)	OPERATING PROCEDURE FOR QUARTERLY ETHYLENE OXIDE BIOBURDEN AUDIT PROGRAM	Released
UM-0000054	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	OPERATING PROCEDURE FOR QUARTERLY PARTICULATE COUNT AUDIT IN CONTROLLED MANUFACTURING AREA & MICRO	Procedure (Non-PPE)	Quality System	Sterilization and Microbiology	46 (47)	OPERATING PROCEDURE FOR THE QUARTERLY PARTICULATE COUNT AUDIT CONDUCTED INSIDE THE CONTROLLED MANUFACTURING ENVIRONMENT (ENVIRONMENT CONTROL LEVEL #2) AND MICROBIOLOGY DEPARTMENT	Released
UM-0000055	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	OPERATING PROCEDURE FOR Viable AIRBORNE AND SURFACE MONITORING CONDUCTED IN THE CME	PPE Work Instruction	Manufacturing Instruction	Sterilization Environmental	63	OPERATING PROCEDURE FOR Viable AIRBORNE AND SURFACE MONITORING CONDUCTED INSIDE THE CONTROLLED MANUFACTURING ENVIRONMENT (ENVIRONMENTAL CONTROL LEVEL #2)	Released
UM-0000056	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Franchise Procedure for Dry Heat Sterilization	Procedure (Non-PPE)	Quality System	Sterilization and Microbiology	8	na	Released
UM-0000068	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Franchise Procedure for ENVIRONMENTAL CONTROL	Procedure (Non-PPE)	Environmental Health and Safety	Environmental Health and Safety	4	Franchise Procedure for ENVIRONMENTAL CONTROL	Released
UM-0000136	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Franchise Procedure for Moist Heat Sterilization	Procedure (Non-PPE)	Quality System	Sterilization and Microbiology	3	na	Released
UM-0000144	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Franchise Procedure for Ethylene Oxide (EO) Sterilization	PPE Work Instruction	Manufacturing Instruction	Sterilization and Microbiology	7	Franchise Procedure for Ethylene Oxide (EO) Sterilization	Released
UM-0000145	Ethicon-Somerville-Research and Development-Sterilization Sciences and Technology	Franchise Procedure for Controlled Manufacturing Environments	Procedure (Non-PPE)	Quality System	Facilities and Maintenance	5	na	Released
100024871	Ethicon Products,	Ethiloop Risk Management Report	Risk Management Document	Risk Management Report		1	Ethiloop Risk Management Report	Released
100036128	Women's Health and Urology,	ArtisYn RMR	Risk Management Document	Risk Management Report		2	Risk Management Report ArtisYn Y-Shaped Mesh	Released
100048385	Ethicon Products,	Risk Management Report for Dermabond Prineo	Risk Management Document	Risk Management Report		1	Risk Management Report for Dermabond Prineo	Released
PS-0000213	Ethicon Products,	RMR-0000010, Risk Management Report for Pronova - PVDF Sutures	Risk Management Document	Risk Management Report		6	RMR-0000010, Risk Management Report for Pronova - PVDF - Sutures	Released
PS-0000214	Ethicon Products,	Risk Management Report for MONOCRYL® Plus Antibacterial Sutures	Risk Management Document	Risk Management Report		9	Risk Management Report for MONOCRYL® Plus Antibacterial Sutures	Released
PS-0000215	Ethicon Products,	Risk Management Report for European CR Monocryl manufactured in San Angelo, TX.	Risk Management Document	Risk Management Report		4 (OBS)	Risk Management Report for European CR Monocryl manufactured in San Angelo, TX.	Released
PS-0000216	Ethicon Products,	Risk Management Report for the GYNECARE PROFIX Fastener System	Risk Management Document	Risk Management Report		1	Risk Management Report for the GYNECARE PROFIX Fastener System	Released
PS-0000221	Ethicon Products,	Risk Management Report (RMR) for the TVT Laser Cut Mesh (LCM) Project	Risk Management Document	Risk Management Report		3	Risk Management Report (RMR) for the TVT Laser Cut Mesh (LCM) Project	Released
PS-0000282	Ethicon Products,	Risk Management Report for PROCEED® Surgical Mesh	Risk Management Document	Risk Management Report		4	Risk Management Report for PROCEED® Surgical Mesh	Released

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PS-0000289	Ethicon Products,	Converting VICRYL LIGATURE Product into Zipper Organized Tray.	Risk Management Document	Risk Management Report		3	Converting VICRYL LIGATURE Product into Zipper Organized Tray.	Released
PS-0000308	Ethicon Products,	RMR for TVT SECUR	Risk Management Document	Risk Management Report		2	RMR for TVT SECUR	Released
PS-0000314	Women's Health and Urology,	RMR for the Morcellex (MX0100)	Risk Management Document	Risk Management Report		4	RMR for the Morcellex (MX0100)	Released
PS-0000315	Women's Health and Urology,	Legacy RM Report for INTERCEED (TC7)	Risk Management Document	Risk Management Report		4	Legacy RM Report for INTERCEED (TC7)	Released
PS-0000345	Ethicon Products,	Risk Management Report for PDS Plus Antibacterial Sutures.	Risk Management Document	Risk Management Report		8	Risk Management Report for PDS Plus Antibacterial Sutures.	Released
PS-0000346	Women's Health and Urology,	Risk Management Report (RMR) for the GYNECARE PROSIMA Pelvic Floor Repair Kit - Project MINT	Risk Management Document	Risk Management Report		2	Risk Management Report (RMR) for the GYNECARE PROSIMA Pelvic Floor Repair Kit - Project MINT	Released
PS-0000389	Ethicon Products,	Risk Management Report for Coated VICRYL® Plus Antibacterial (Polyglactin 910) Sutures	Risk Management Document	Risk Management Report		3 (4)	Risk Management Report for Coated VICRYL® Plus Antibacterial (Polyglactin 910) Sutures	Released
PS-0000401	Ethicon Products,	Risk Management Report for ETHIBOND/ETHIBOND EXCEL Coated Polyester Sutures	Risk Management Document	Risk Management Report		3	Risk Management Report for ETHIBOND/ETHIBOND EXCEL Coated Polyester Sutures	Released
PS-0000425	Ethicon Products,	Risk Management Report for Mersilene Polyester Sutures and Tape	Risk Management Document	Risk Management Report		1 (2)	Risk Management Report for Mersilene Polyester Sutures and Tape	Released
PS-0000435	Women's Health and Urology,	Risk Management Report for PROLIFT+M Pelvic Floor Repair Systems	Risk Management Document	Risk Management Report		5	Risk Management Report for PROLIFT+M Pelvic Floor Repair Systems	Released
PS-0000436	Women's Health and Urology,	RISK MANAGEMENT REPORT THERMACHOICE III	Risk Management Document	Risk Management Report		5	RISK MANAGEMENT REPORT THERMACHOICE III	Released
PS-0000437	Women's Health and Urology,	RISK MANAGEMENT REPORT(LEGACY) FOR TVT AND TVT-O	Risk Management Document	Risk Management Report		2	RISK MANAGEMENT REPORT(LEGACY) FOR TVT AND TVT-O	Released
PS-0000438	Women's Health and Urology,	Morcellation Motor Drive Unit Compatible with X-TRACT and MORCELLEX disposable morcellators	Risk Management Document	Risk Management Report		1	Morcellation Motor Drive Unit Compatible with X-TRACT and MORCELLEX disposable morcellators	Released
PS-0000439	Ethicon Products,	Risk Management Report for NUVANCE® FACIAL REJUVENATION SYSTEM	Risk Management Document	Risk Management Report		2	Risk Management Report for NUVANCE® FACIAL REJUVENATION SYSTEM	Released
PS-0000440	Ethicon Products,	Risk Management Report for Bone Wax	Risk Management Document	Risk Management Report		3	Risk Management Report for Bone Wax	Released
PS-0000486	Ethicon Products,	Legacy risk management report for Blue Ethilon	Risk Management Document	Risk Management Report		2	Legacy risk management report for Blue Ethilon	Released
PS-0000486	Women's Health and Urology,	Legacy risk management report for Gyremesh®PS	Risk Management Document	Risk Management Report		1	Legacy risk management report for Gyremesh®PS	Released
PS-0000487	Women's Health and Urology,	Legacy Risk Management Report for Gynecare PROLIFT; Pelvic Floor Repair System	Risk Management Document	Risk Management Report		1	Legacy Risk Management Report for Gynecare PROLIFT; Pelvic Floor Repair System	Released
PS-0000488	Ethicon Products,	Legacy risk management report for Prolene 3D Patch	Risk Management Document	Risk Management Report		1	Legacy risk management report for Prolene 3D Patch	Released
PS-0000488	Ethicon Products,	Legacy risk management report for Prolene Hernia System	Risk Management Document	Risk Management Report		1	Legacy risk management report for Prolene Hernia System	Released
PS-0000489	Ethicon Products,	Legacy Risk management report for Prolene mesh	Risk Management Document	Risk Management Report		1	Legacy Risk management report for Prolene mesh	Released
PS-0000489	Ethicon Products,	Legacy risk management report for X-tract Morcellator	Risk Management Document	Risk Management Report		1	Legacy risk management report for X-tract Morcellator	Released
PS-0000492	Ethicon Products,	Legacy risk management report for Vicryl Mesh	Risk Management Document	Risk Management Report		1	Legacy risk management report for Vicryl Mesh	Released
PS-0000492	Ethicon Products,	Risk Management Report for the Blake / J-VAC Closed Drain systems.	Risk Management Document	Risk Management Report		2	Risk Management Report for the Blake / J-VAC Closed Drain systems.	Released
PS-0000513	Ethicon Products,	Legacy risk management report for Proxi-Strip Skin Closure	Risk Management Document	Risk Management Report		1	Legacy risk management report for Proxi-Strip Skin Closure	Released
PS-0000513	Ethicon Products,	Legacy risk management report for Surgical Polypropylene Buttons	Risk Management Document	Risk Management Report		1	Legacy risk management report for Surgical Polypropylene Buttons	Released
PS-0000515	Ethicon Products,	Legacy risk management report for PDS II Sutures.	Risk Management Document	Risk Management Report		3 (4)	Legacy risk management report for PDS II Sutures.	Released
PS-0000515	Ethicon Products,	Legacy risk management report for Prolene Suture	Risk Management Document	Risk Management Report		2	Legacy risk management report for Prolene Suture	Released
PS-0000516	Ethicon Products,	Legacy risk management report for Retention Suture Bridge.	Risk Management Document	Risk Management Report		1	Legacy risk management report for Retention Suture Bridge.	Released
PS-0000516	Ethicon Products,	Legacy risk management report for Surgical Stainless Steel Suture.	Risk Management Document	Risk Management Report		2	Legacy risk management report for Surgical Stainless Steel Suture.	Released
PS-0000517	Ethicon Products,	Risk Management Report for Silk Suture	Risk Management Document	Risk Management Report		3	Risk Management Report for Silk Suture	Released
PS-0000517	Women's Health and Urology,	Legacy risk management report for Gynecare Versascope Sheath and Outflow Cannula	Risk Management Document	Risk Management Report		1	Legacy risk management report for Gynecare Versascope Sheath and Outflow Cannula	Released
PS-0000519	Ethicon Products,	Legacy risk management report for Nurolon Nylon Sutures	Risk Management Document	Risk Management Report		1	Legacy risk management report for Nurolon Nylon Sutures	Released
PS-0000519	Ethicon Products,	Risk Assessment for Umbilical Tape and Radiopaque Umbilical Tape.	Risk Management Document	Risk Management Report		2	Risk Assessment for Umbilical Tape and Radiopaque Umbilical Tape.	Released

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PS-0000520	Ethicon Products,	Legacy risk management report for Monocryl Suture	Risk Management Document	Risk Management Report		1 (2)	Legacy risk management report for Monocryl Suture	Released
PS-0000520	Ethicon Products,	Risk management report for Ethilon Nylon Suture	Risk Management Document	Risk Management Report		4	Risk management report for Ethilon Nylon Suture	Released
PS-0000521	Ethicon Products,	Legacy risk management report for Ethicon TFE Polymer Pledgets.	Risk Management Document	Risk Management Report		1	Legacy risk management report for Ethicon TFE Polymer Pledgets.	Released
PS-0000521	Ethicon Products,	Risk management report for Vicryl Sutures.	Risk Management Document	Risk Management Report		2	Risk management report for Vicryl Sutures.	Released
PS-0000522	Women's Health and Urology,	Legacy risk management report for Versascope Instruments.	Risk Management Document	Risk Management Report		1	Legacy risk management report for Versascope Instruments.	Released
PS-0000522	Women's Health and Urology,	Risk Management Report for Gynecare TVT EXACT	Risk Management Document	Risk Management Report		4	Risk Management Report for Gynecare TVT EXACT	Released
PS-0000523	Women's Health and Urology,	RISK MANAGEMENT REPORT FOR GYNECARE TVT ABBREVO	Risk Management Document	Risk Management Report		3	RISK MANAGEMENT REPORT FOR GYNECARE TVT ABBREVO	Released
PS-0000523	Ethicon Products,	SECURESTRAP Fixation Device Product Family	Risk Management Document	Risk Management Report		5	SECURESTRAP Fixation Device Product Family	Released
PS-0000524	Ethicon Products,	EVERPOINT RMR	Risk Management Document	Risk Management Report		7	EVERPOINT RMR	Released
PS-0000524	Ethicon Products,	Risk Management Report for Temporary Cardiac Pacing Wire (TPW) product family.	Risk Management Document	Risk Management Report		1	Risk Management Report for Temporary Cardiac Pacing Wire (TPW) product family.	Released
PS-0000538	Ethicon Products,	To create a new Risk Management Report for MERSILENET Suture MERSUTURE Suture to meet the requirements per PR602-003 Rev.19	Risk Management Document	Risk Management Report		1	To create a new Risk Management Report for MERSILENET Suture MERSUTURE Suture to meet the requirements per PR602-003 Rev.19	Released
PR-0011372		Reklamationsmanagement bei Medizinprodukten (SOP 3-01)	Procedure (Non-PPE)			1		
PR-0011373		Mitarbeiter Schulung (SOP 1-04)	Procedure (Non-PPE)			1		
PR-0011374		Prüfung und Freigabe von Werbe- und Schulungsmaterialien (SOP 2-01)	Procedure (Non-PPE)			1		
PR-0011375		Einrichtung und Freigabe neuer Produkte / Artikelnummern (Handelsware) (SOP 2-02)	Procedure (Non-PPE)			1		
PR566-005		FRANCHISE WORK INSTRUCTIONS FOR MEDICAL DEVICE VIGILANCE SYSTEM	Procedure (Non-PPE)			25		
100074123	Ethicon Products,	Operating Procedure for Inspection, Maintenance, Calibration and Use of the Hewlett-Packard 5890 Gas Chromatograph with HP Chemstation	Work Instruction (Non-PPE)	Quality System	Calibration and Measuring Equipment	3	Operating Procedure for Inspection, Maintenance, Calibration and Use of the Hewlett-Packard 5890 Gas Chromatograph with HP Chemstation	Released